L Number	Hits	Search Text	DB	Time stamp
1	1900	lee.in. with robert	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:47
2	0	loethe.in. with brian	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:47
3	1	koethe.in. with brian	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:47
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6	30	((lee.in. with robert) (koethe.in. with brian) (swaback.in. with theodore)) and syringe	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:49
9	1	09/584307	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:54
10	17	("3810469" | "4254768" | "4506455" | "4693706" | "5435076" | "5531683" | "5643218" | "5685846" | "5697915" | "5709666" | "5743886" | "5769825" | "5779668" | "5788670" | "5833653" | "5865803" | "5971953").PN.	USPAT	2004/01/25 16:50
11	8	("3672369" | "4030498" | "4632672" | "4846801" | "5125898" | "5238003" | "5318536" | "5489266").PN.	USPAT	2004/01/25 16:52
13	610	604/228	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:55
14	324	((604/228) or (604/231)).CCLS.	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:55
15	706	604/228 (((604/228) or (604/231)).CCLS.)	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:55
16	632	(604/228 (((604/228) or (604/231)).CCLS.)) and @PD<=20011221	USPAT; US-PGPUB; EPO; JPO	2004/01/25 17:17
17	6	("4059109" | "4233975" | "4687487" | "4863427" | "4880410" | "4973308").PN.	USPAT	2004/01/25 17:08
19	876	(syringe with vent$) and @PD<=20011221	USPAT; US-PGPUB; EPO; JPO	2004/01/25 17:18
21	262	(syringe same (plunger piston) with vent$) and @PD<=20011221	USPAT; US-PGPUB; EPO; JPO	2004/01/25 17:19
22	240	((syringe same (plunger piston) with vent$) and @PD<=20011221) not ((604/228 (((604/228) or (604/231)).CCLS.)) and @PD<=20011221)	USPAT; US-PGPUB; EPO; JPO	2004/01/25 17:19

US-PAT-NO: 4813938

DOCUMENT-IDENTIFIER: US 4813938 A

TITLE: Catheter introduction syringe

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DATE ISSUED - PD (1):
19890321

Detailed Description Text - DETX (20):
In use, the substantially cylindrical plunger 14" is inserted into the substantially cylindrical syringe barrel 12" with the plunger vent seal 92" preferably against the finger grasping element 20" with the plunger vent 90" open. The substantially cylindrical plunger 14" is then fully retracted as barrel vent 84" is occluded. The positive pressure created inside the hollow substantially cylindrical syringe barrel 12" is transmitted into the interior of the second plunger element 24" through the plunger vent 90". The plunger vent 90" is then sealed by the plunger vent seal 92" and the positive pressure within the interior of the second plunger element 24" maintained when the second plunger element 24" is fully retracted. When the barrel vent 84" is opened to atmospheric pressure, the plunger vent seal 92" remains over the plunger vent 90" as the catheter introduction syringe 10" is aspirated or flushed. The positive pressure within the second plunger element 24" maintains the sealing integrity of the second valve element 96".

Claims Text - CLTX (11):
11. The catheter introduction syringe of claim 10

wherein said syringe
barrel and said plunger include a barrel vent and plunger
vent respectively
formed therethrough, and a plunger vent seal slidably
mounted on said plunger
to seal said plunger vent when said barrel vent is occluded
and said plunger is
retracted relative to said syringe barrel to creater a
positive pressure within
said second plunger element to maintain the sealing
integrity of said second
valve element.

United States Patent [19]

Raulerson

[11] **Patent Number: 4,813,938**

[45] **Date of Patent: Mar. 21, 1989**

[54] **CATHETER INTRODUCTION SYRINGE**

[76] Inventor: **J. Daniel Raulerson**, 1203 Belleville Ave., Brewton, Ala. 36426

[21] Appl. No.: **97,758**

[22] Filed: **Sep. 17, 1987**

[51] **Int. Cl.**[4] **A61M 5/00**

[52] **U.S. Cl.** **604/167**; 604/236; 604/156; 604/169

[58] **Field of Search** 251/149.1, 149.3, 149; 604/167, 169, 156, 159, 124, 125, 236; 137/223

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,274,408	6/1981	Nimrod	604/52 X

FOREIGN PATENT DOCUMENTS

2415196	10/1975	Fed. Rep. of Germany	604/159
2507119	9/1976	Fed. Rep. of Germany	604/159
3042229	5/1982	Fed. Rep. of Germany	604/167

Primary Examiner—Samuel Scott

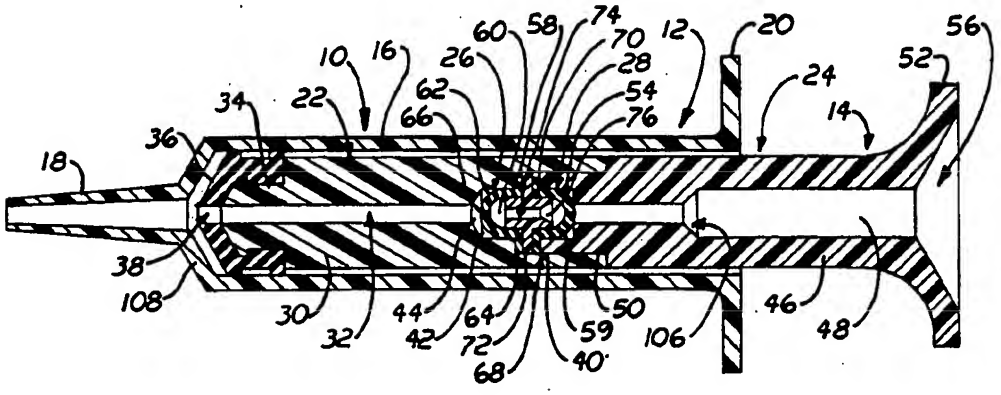
Assistant Examiner—Carl D. Price

Attorney, Agent, or Firm—A. W. Fisher, III

[57] **ABSTRACT**

A catheter introduction syringe for the introduction of a catheter or catheter guide wire into a patient's body, the catheter introduction syringe comprises a hollow substantially cylindrical syringe barrel to support a needle thereon having a substantially cylindrical plunger slidably disposed therein, the substantially cylindrical plunger includes a centrally disposed channel formed longitudinally therethrough having a valve assembly disposed in operative relationship relative to the centrally disposed channel to prevent passage of air or liquid therethrough during flushing or aspirating of the catheter introduction syringe and permit the introduction of a catheter or catheter guide wire through the centrally disposed channel, hollow substantially cylindrical syringe barrel and needle for introduction into the patient's body without the flow of air or liquid through the centrally disposed channel.

20 Claims, 1 Drawing Sheet



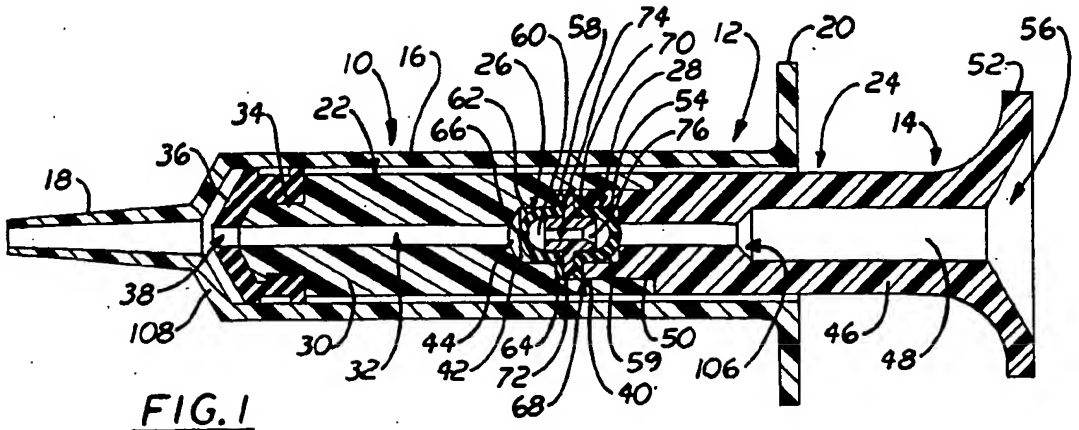


FIG. 1

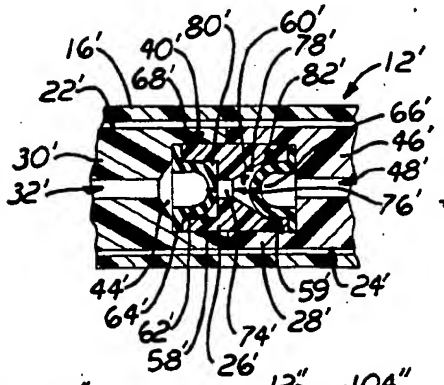


FIG. 2

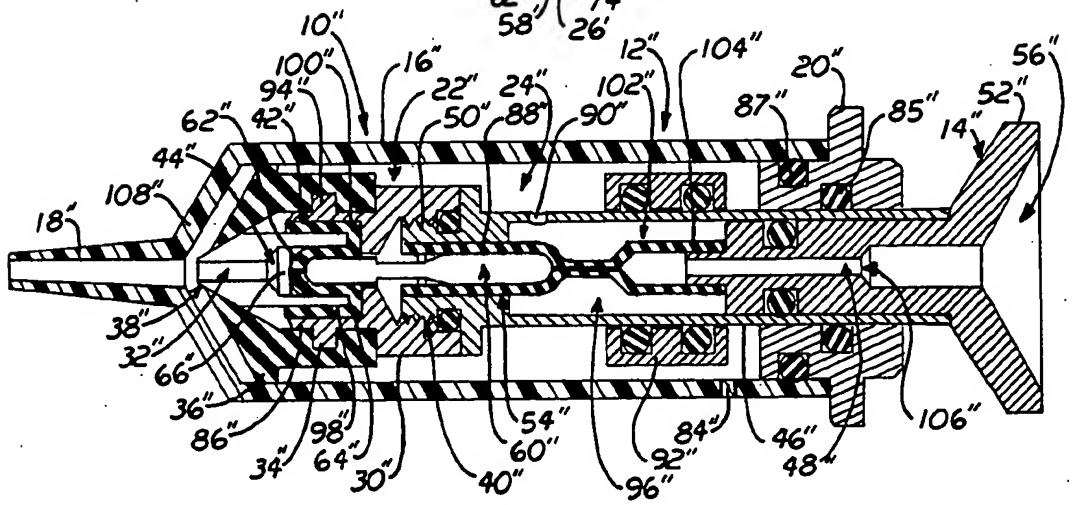


FIG. 3

CATHETER INTRODUCTION SYRINGE

BACKGROUND OF THE INVENTION

1. Field of the Invention

A catheter introduction syringe comprising a barrel and plunger combination wherein the plunger includes a centrally disposed passage having a valve assembly disposed therein to prevent the flow of fluid therethrough and permit the introduction of a catheter.

2. Description of the Prior Art

The art of introducing a catheter into a patient's body is difficult and often dangerous.

Commonly the central venous catheter placement is performed in the following manner:

(1) The patient is placed in Trendelenburg position to distend the thoracic veins if the internal jugular or subclavian veins are to be cannulated. The patient is placed in a flat supine position for cannulation of the femoral veins.

(2) Using body landmarks, identified visually or by palpation, the vein is indentified by aspiration of blood. This is accomplished by gently aspirating a syringe as the needle is advanced. Once blood appears in the syringe presence of the needle within the lumen of the vein is confirmed.

(3) In cannulation, catheter-over-needle catheter is advanced off the needle and down (or up) the vein, or; the syringe is removed from the needle and a catheter is threaded through the needle and into the vein, or; the syringe is removed from the needle and a guidewire is threaded through the needle and into the vein lumen. The needle is then removed leaving the catheter or guidewire in place. If the guidewire is used a catheter is threaded over the guidewire and down the lumen of the vein and the guidewire is removed.

In deep vein cannulation, the deep veins of the chest are exposed to the pressures created by respiration. During the inspiratory phase of respiration negative pressure is transmitted to the veins. In expiration positive pressure is transmitted to the veins. Therefore, if a subclavian or internal jugular vein is exposed to atmospheric pressure blood will pass from the vein during expiration while air will be pulled into the vein during inspiration. It is this latter situation which creates a potentially dangerous condition. If enough air enters the vein and goes to the heart it can result in an air embolus to the brain with the development of a stroke.

Numerous devices have been developed and used for catheter introduction.

For example, U.S. Pat. 4,274,408 discloses a syringe-type device for inserting a catheter guide wire into a blood vessel including a syringe in which the plunger has a central passage extending through it. A thin feeder tube including a central passge is slidably disposed in the central passage of the plunger. The plunger passage is normally blocked by a sphere received in a seat provided by a rubber tip on inner edge of the plunger body. The needle is inserted into the blood vessel and the plunger is then partially withdrawn to permit blood to be observed in the body of the syringe for verification of proper needle positioning. The thin feeder tube is then slid through the central passage past the sphere to eject the sphere to open the plunger passage. The thin feeder tube is further advanced to bring the inner end into contact with the end wall of the syringe. In this position, the central passage of the thin feeder tube is aligned and in communication with the needle lumen. A catheter guide wire may then be fed into the blood vessel by sliding it through the central passage of the thin feeder tube and the needle lumen. The device is then removed from the guide wire, and a beveled catheter is inserted over the guide wire in the usual manner.

U.S. Pat. Nos. 4,233,982; 4,245,635 and 4,261,357 also show catheter assemblies for intravenous use including a ball or spherical element to selectively operate as a vale sealing means.

U.S. Pat. No. 4,483,340 discloses a dilation catheter including a balloon element configured to be retracted by axial twisting following deflation.

U.S. Pat. No. 4,314,555 shows an intravascular catheter comprising a flexible catheter tube having the proximal end affixed to the distal end of a tubular hub of a catheter. A seal cap is connected to the catheter hub with a flexible tube disposed between the seal cap and catheter hub. The inner wall thereof closely abuts against the outer wall of a cannula which guides the catheter through the blood vessel. A location bar is fixed to a hub of the cannula and protrudes toward the distal end of the catheter. A stopper is mounted on the catheter hub to engage the distal end of the location bar.

U.S. Pat. No. 4,601,706 shows a central venous pressure catheter having a long flexible tube containing at least three channels or lumens. At the tip end of the catheter a balloon surrounds the tube and is inflatable via one of the channels. A distal port and a proximal port in the wall of the tube are located on either side of the balloon, and are connected to the other two channels respectively. The tip end of the catheter may be inserted through a jugular vein into a patient's superior cava vein near the heart. The balloon is inflated to partially obstruct the flow of blood and to increase the blood pressure at a site of surgery at the head or neck of a patient in the upright position to avoid air embolism as well as to prevent bleeding.

U.S. Pat. No. 3,215,141 discloses an apparatus for use in intravenous introduction of a fluid comprising an elongate hollow needle of uniform inner and outer diameter. One end of the needle is formed to provide a sharpened edge for making a vein puncture. A tubular needle holder is removably mounted upon the opposite end of the needle. A sleeve is fitted over the needle holder. A pliable sac is secured at one end to the outer surface of the sleeve and extends rearwardly therefrom. The opposite end of the sac is sealed. A flexible catheter is positioned within the sac with one end in the needle and extendable outwardly of thereof by manipulation through the sac. The uniform outer diameter of the the needle permits positioning flatly against a patient's body after withdrawal of the needle from the vein puncture and removal of the needle holder from the needle.

U.S. Pat. No. 4,517,979 shows a detachable balloon catheter comprising a sealing valve assembly having an elongated passageway extending therethrough. An inflatable balloon having a mouth portion is bonded to the periphery of the sealing valve assembly. A small diameter cannula having a distal end which extends through the passageway in the sealing valve assembly. The small diameter cannula includes a connector terminal on the proximal end which is adapted to be coupled to a source of fluid pressure. The sealing valve assembly includes a valve mechanism which permits the passage of the cannula through the passageway but prevents the flow of

fluid through the passagewan when the cannula is removed.

U.S. Pat. No. 4,160,383 shows a unitary vent-valve assembly, useful in urological applications.

U.S. Pat. Nos. 2,936,756; 3,097,646; 3,308,820; 3,766,916; 3,853,127; 3,859,998; 4,029,104; 4,177,814; 4,200,096; 4,346,698; 4,424,833; 4,529,399; 4,606,347; 4,610,665 and France Patent No. 2,004,771 show various syringes or medical instruments employing elastomeric plugs or membranes as seals or valves in combination with syringes.

U.S. Pat. Nos. 3,739,778 and 3,851,647 disclose catheter introduction systems using removable plugs to selectively seal fluid or catheter channels.

U.S. Pat. Nos. 105,776; 2,711,734 and 4,356,823 disclose suction control in valve elements movable to selectively control the flow of fluid through a valve body.

U.S. Pat. Nos. 4,243,034 and 4,464,177 show clamping structures to seal or control the flow of fluid.

Additional examples of the prior art are shown in U.S. Pat. Nos. 3,040,743; 3,335,723; 3,920,013; 3,978,863; 4,448,195; 4,479,497 and Italy Patent No. 407,607.

SUMMARY OF THE INVENTION

The present invention relates a catheter introduction syringe for the introduction of a catheter or catheter wire into a patient's body comprising a hollow syringe barrel having a plunger slidably disposed therein. As described more fully hereinafter, the catheter introduction syringe is capable of functioning as a standard air tight syringe as well as a device to introduce a catheter with a minimum resistance to the guide wire or catheter permitting tactile feel during introduction of the guide wire or catheter into the patient's body.

The plunger comprises first and second plunger element and a valve recess cooperatively formed therebetween to operatively house a valve assembly.

The first plunger element includes a first centrally disposed channel formed therethrough and a first valve seat formed therethrough. The second plunger element includes a second centrally disposed channel formed therethrough and a second valve seat formed therein.

The first and second valve seats cooperatively form the valve recess to receive the valve assembly therein. The valve assembly comprises a first and second valve element cooperatively forming a valve chamber therebetween. A normally closed centrally disposed slit or aperture is formed in the center of each valve element.

In use the catheter introduction syringe is aspirated by the retraction of the plunger permitting fluid to pass into the interior of the syringe barrel. During this aspiration, air is prevented from entering the valve chamber by the second valve element. Once aspirated, the catheter introduction syringe may then be flushed. While flushing, the first valve element prevents liquid from passing through the first centrally disposed channel into the valve chamber. Thus the catheter introduction syringe functions as an ordinary syringe.

Then a catheter or guide wire may be passed through the catheter introduction syringe and into the bloood vessel or body. The catheter or guide wire passes through the centrally disposed slits or apertures formed within the valve elements which form a seal therewith to prevent either liquid or air from passing through the valve chamber during the introduction of the catheter or guide wire.

The invention accordingly comprises the features of construction, combination of elements, and arrangement of parts which will be exemplified in the construction hereinafter set forth, and the scope of the invention will be indicated in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and object of the invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

FIG. 1 is a cross-section side view of the catheter introduction syringe.

FIG. 2 is a detailed cross-sectional side view of an alternate embodiment of the valve assembly.

FIG. 3 is a cross-sectional side view of an alternate embodiment of the catheter introduction syringe.

Similar reference characters refer to similar parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

As shown in FIG. 1 the present invention relates a catheter introduction syringe generally indicated as 10 for the introduction of a catheter or catheter wire into a patient's body comprising a hollow substantially cylindrical syringe barrel generally indicated as 12 having a substantially cylindrical plunger generally indicated as 14 slidably disposed therein. As described more fully hereinafter, the catheter introduction syringe 10 is capable of functioning as a standard air tight syringe as well as a device to introduce a catheter with minimum resistance to the guide wire or catheter permitting tactile feel during introduction of the guide wire or catheter into the patient's body.

The hollow substantially cylindrical syringe barrel 12 comprises a hollow substantially cylindrical body 16 having a hollow barrel tip 18 to receive a needle (not shown) and a finger grasping element 20 formed on opposite ends thereof.

The substantially cylindrical plunger 14 comprises first and second plunger elements generally indicated as 22 and 24 respectively and a valve recess generally indicated as 26 cooperatively formed therebetween to operatively house a valve assembly generally indicated as 28 therein.

The first plunger element 22 comprises a first substantially cylindrical body 30 having a first centrally disposed channel 32 formed therethrough. One end of the first substantially cylindrical body 30 includes a reduced portion 34 to receive a plunger seal 36 having a centrally disposed seal aperture 38 formed therein, while the opposite end thereof includes a countersunk recess 40 to receive a portion of the second plunger element 24. A first valve seat 42 having a conical alignment recess 44 is formed between the countersunk recess 40 and the first centrally disposed channel 32.

The second plunger element 24 comprises a second substantially cylindrical body 46 having a second centrally disposed channel 48 formed therethrough. The inner end of the second substantially cylindrical body 46 includes a reduced portion 50 to be received within the countersunk recess 40 of the first substantially cylindrical body 30, while the opposite end includes a thumb element or rest 52 having a conical alignment guide recess 56 formed therein. A second valve seat 54 is formed on the inner end of the reduced portion 50 of the second substantially cylindrical body 46.

The first and second valve seats 42 and 54 cooperatively form the valve recess 26 to receive the valve assembly 28 therein. The valve assembly 28 comprises first and second one-way valve elements generally indicated as 58 and 59 respectively to cooperatively form a valve chamber 60 therebetween. Valve elements 58 and 59 comprise a flexible resilient hollow substantially hemispheric member 62 having an annular flange 64 formed about the periphery thereof. A normally closed centrally disposed slit or aperture 66 is formed in the center of each flexible resilient hollow substantially hemispheric member 62. To limit movement or deflection of the first and second valve elements 58 and 59 and maintain the sealing integrity thereof, a rigid valve support element generally indicated as 68 is disposed within the valve chamber 60. The rigid valve support element 68 comprises a substantially cylindrical body 70 having an annular flange 72 formed about the mid-portion thereof. The annular flange 72 is disposed between the annular flanges 64. A centrally disposed channel 74 including a conical alignment recess 76 is formed through the substantially cylindrical body 70. The conical alignment guide recess 56, conical alignment recess 76 and conical alignment recess 44 cooperatively form a catheter alignment means.

In use the catheter introduction syringe 10 is aspirated by the retraction of the substantially cylindrical plunger 14 permitting fluid to pass into the interior of the substantially cylindrical syringe barrel 12 through the hollow barrel tip 18. During this aspiration air is prevented from entering the valve chamber 60 by the second valve element 59. Once aspirated, the catheter introduction syringe 10 may then be flushed. While flushing, the first valve element 58 prevents liquid from passing through the first centrally disposed channel 32 into the valve chamber 60. Thus the catheter introduction syringe 10 functions as an ordinary syringe.

Then a catheter or guide wire may be passed through the catheter introduction syringe 10 and into the blood vessel or body cavity using the catheter aligned means. The catheter or guide wire passes through the centrally disposed slots or apertures 66 formed in the first and second valve elements 58 and 59 which form a seal therewith to prevent either liquid or air from passing through the valve chamber 60 during the introduction of the catheter of guide wire.

An alternate embodiment of the valve assembly 28' is shown in FIG. 2. The first plunger element 22' comprises a first substantially cylindrical body 30' having a first centrally disposed channel 32' formed therethrough. One end thereof includes a countersunk recess 40' having a conical alignment recess 44' formed between the countersunk recess 40' and the first centrally disposed channel 32'. The second plunger element 24' comprises a second substantially cylindrical body 46' having a second centrally disposed channel 48' formed therethrough. The inner end of the second substantially cylindrical body 46' includes a countersunk recess 78'.

The countersunk recesses 40' and 78' cooperatively form the valve recess 26' to receive the valve assembly 28 therein. The valve assembly 28' comprises first and second one-way valve elements generally indicated as 58' and 59' respectively disposed within a first and second valve seat generally indicated as 80' and 82' respectively cooperating forming a valve chamber 60' therebetween.

First and second valve elements 58' and 59' comprise a flexible resilient hollow substantially hemispheric member 62' having an annular flange 64' formed about the periphery thereof. A normally closed centrally disposed slit or aperture 66' is formed in the center of each flexible resilient hollow substantially hemispheric member 62'. To limit movement or deflection of the first and second valve elements 58' and 59' and maintain the sealing integrity thereof, the first and second valve seats 80' and 82' are formed within a rigid valve support element generally indicated as 68' disposed within the valve recess 26'. The rigid valve support element 68' includes a centrally disposed channel 74' extending between the first and second valve seat 80' and 82'. A conical alignment recess 76' is formed within the rigid valve support element 68'. The conical alignment guide recess 56', conical alignment recess 76' and conical alignment recess 44' cooperatively form a catheter alignment means.

The alternate embodiment of the valve assembly 28' functions similarly to that of the first embodiment as described above.

FIG. 3 shows an alternate embodiment of the catheter introduction syringe 10''.

The hollow substantially cylindrical syringe barrel 12'' comprises a hollow substantially cylindrical body 16'' having a hollow barrel tip 18'' to receive a needle (not shown) and a finger grapsing element 20'' formed on opposite ends thereof. A barrel vent 84'' is formed through the sidewall of the hollow substantially cylindrical body 16'' preferably near the finger grasping element 20''. The finger grasping element 20'' further includes a syringe barrel sealing means comprising inner and outer sealing elements indicated as 85'' and 87'' respectively to form air tight seals between the substantially cylindrical plunger 14'' and finger grasping element 20'' and between the finger grasping element 20'' and the hollow substantially cylindrical syringe barrel 12'' respectively.

The substantially cylindrical plunger 14'' comprises first and second plunger elements generally indicated as 22'' and 24'' respectively and a valve recess means to operatively house a valve assembly means.

The first plunger element 22'' comprises a first substantially cylindrical body 30'' having a first centrally disposed channel 32'' formed therethrough. One end of the first substantially cylindrical body 30'' includes a reduced portion 34'' to receive a plunger seal 36'' having a centrally disposed seal aperture 38'' formed therein, while the opposite end thereof includes a countersunk recess 40'' to receive a portion of the second plunger element 24''. A first valve seat including a conical alignement recess 44 is formed in the first plunger element 22''.

The second plunger element 24'' comprises a second substantially cylindrical body 46'' having a second centrally disposed channel 48'' formed therethrough. The inner end of the second substantially cylindrical body 46'' includes a reduced portion 50'' to be received within the countersunk recess portion 40'' of the first substantially cylindrical body 30'' while the opposite end includes a thumb element or rest 52'' having a conical alignment guide recess 56'' formed therein. A second valve seat 88'' is formed on the inner end of the reduced portion 50'' of the second substantially cylindrical body 46''. A plunger vent 90'' is formed through the side wall of the second plunger element 24''. A plunger vent seal 92'' is slidably mounted on the second substantially cylindrical body 46'' to selectively seal the plunger vent 90'' as described more fully hereafter.

The first and second valve seats 86" and 88" cooperatively form the valve recess means to receive a portion of the valve assembly means therein. The valve assembly means comprises a first and second valve element generally indicated as 94" and 96" respectively to cooperatively form a valve chamber 60" therebetween. The first valve element 94" comprises a flexible resilient hollow substantially hemispheric member 62" having an annular flange 64" formed about the periphery thereof. A normally closed centrally disposed slit or aperture 66" is formed in the center of the flexible resilient hollow substantially hemispheric member 62". A substantially cylindrical skirt 98" is formed on the annular flange 64" to limit movement or deflection of the first valve element 94" and maintain the sealing integrity thereof by engaging the sidewall 100" of the first valve seat 86". The second valve element 96" comprises a flexible resilient hollow tube generally indicated as 102" extending between the second valve seat 88" and a coupling element 104" extending from the inner end of the thumb element or rest 52". The cross-sectional diameter of the mid-portion of the flexible resilient hollow tube 102" is reduced to form the normally closed centrally disposed slit or aperture 66". The conical alignment recess 56" tapered alignment guide 106" and conical alignment recess 44" cooperatively form a catheter alignment means.

In use, the substantially cylindrical plunger 14" is inserted into the substantially cylindrical syringe barrel 12" with the plunger vent seal 92" preferably against the finger grasping element 20" with the plunger vent 90" open. The substantially cylindrical plunger 14" is then fully retracted as barrel vent 84" is occluded. The positive pressure created inside the hollow substantially cylindrical syringe barrel 12" is transmitted into the interior of the second plunger element 24" through the plunger vent 90". The plunger vent 90" is then sealed by the plunger vent seal 92" and the positive pressure within the interior of the second plunger element 24" maintained when the second plunger element 24" is fully retracted. When the barrel vent 84" is opened to atmospheric pressure, the plunger vent seal 92" remains over the plunger vent 90" as the catheter introduction syringe 10" is aspirated or flushed. The positive pressure within the second plunger element 24" maintains the sealing integrity of the second valve element 96".

When the catheter introduction syringe 10" is aspirated fluid passes into the hollow substantially cylindrical barrel 12" through the hollow barrel tip 18". During this aspiration air is prevented from entering the valve chamber 60" by the second valve element 96". Once aspirated, the catheter introduction syringe 10" may then be flushed. While flushing, the first valve element 94" prevents liquid from passing through the first centrally disposed channel 32" into the valve chamber 60". Thus the catheter introduction syringe 10" functions as an ordinary syringe.

Then a guidewire or catheter can be passed through the catheter introduction syringe 10" and into a blood vessel or body cavity as previously described.

The catheter alignment means may further include a conical alignment recess 106" formed in the second centrally disposed channel 48" and a conically shaped inner end 108" of the hollow substantially cylindrical syringe barrel tip 18.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Now that the invention has been described,

What is claimed is:

1. A catheter introduction syringe for the introduction of a catheter or catheter guide wire into a patient's body, said catheter introduction syringe comprises a hollow syringe barrel to support a needle thereon having a plunger slidably disposed therein, said plunger comprises a first and second plunger element including a first and second valve seat respectively to cooperatively form a valve recess to operatively house a valve assembly therein and a centrally disposed channel formed longitudinally therethrough including a first and second centrally disposed channels formed through said first and second plunger elements respectively, said first and second centrally disposed channels disposed on opposite sides of said valve assembly, said valve assembly comprises a first and second valve element each including a flexible resilient valve member having a normally closed centrally disposed slit formed therein disposed within said first and second valve seats respectively to cooperatively form a valve chamber therebetween and a rigid valve support element disposed within said valve chamber arranged to limit deflection of said first and second valve elements and to maintain the sealing integrity thereof, said valve assembly disposed in operative relationship relative to said centrally disposed channel to prevent passage of air or liquid therethrough during flushing or aspirating of said catheter introduction syringe and permit the introduction a catheter or catheter guide wire through centrally disposed channel, said hollow syringe barrel and needle for introduction into the patient's body without the flow of air or liquid through said centrally disposed channel.

2. The catheter introduction syringe of claim 1 wherein each said flexible resilient valve member comprise a hollow substantially hemispheric member.

3. The catheter introduction syringe of claim 1 wherein said rigid valve support element comprises a body having a centrally disposed channel formed therethrough.

4. The catheter introduction syringe of claim 3 wherein said first plunger element includes a conical alignment recess formed therein and said rigid valve support element includes a conical alignment recess formed adjacent said centrally disposed channel to cooperatively form a catheter alignment means.

5. The catheter introduction syringe of claim 4 wherein said catheter alignment means further includes a conical recess formed in said second centrally disposed channel.

6. The catheter introduction syringe of claim 5 wherein said catheter alignment means further includes a conically shaped outer end portion of said syringe barrel.

7. A catheter introduction syringe for the introduction of a catheter or catheter guide wire into a patient's body, said catheter introduction syringe comprises a hollow syringe barrel to support a needle thereon having a plunger slidably disposed therein, said plunger includes a centrally disposed channel formed longitudinally therethrough having a valve assembly including a first and second valve element disposed in operative relationship relative to said centrally disposed channel to prevent passage of air or liquid therethrough during flushing or aspirating of said catheter introduction sy-

ringe and permit the introduction of a catheter or catheter guide wire through said centrally disposed channel, said hollow syringe barrel and needle for introduction into the patient's body without the flow of air or liquid through said centrally disposed channel, said plunger comprises a first and second plunger element including a first and second valve seat respectively to receive said first and second valve element respectively to cooperatively form a valve chamber therebetween, said first valve element comprises a flexible resilient hollow substantially hemispheric member including a normally closed centrally disposed slit formed therein and a annular skirt spaced from and formed about the at least a portion of said first valve element and arranged to engage said first valve seat to limit deflection of said first valve element to maintain the sealing integrity thereof.

8. The catheter introduction syringe of claim 7 wherein said centrally disposed channel comprises a first and second centrally disposed channel formed through said first and second plunger elements respectively, said first and second centrally disposed channels are disposed on opposite sides of said valve assembly.

9. The catheter introduction syringe of claim 7 wherein said second valve element comprise a flexible resilient hollow tube forming a normally closed slit formed in the mid-portion thereof.

10. The catheter introduction syringe of claim 9 further including means to maintain the sealing integrity of said second valve element with said plunger.

11. The catheter introduction syringe of claim 10 wherein said syringe barrel and said plunger include a barrel vent and plunger vent respectively formed therethrough, and a plunger vent seal slidably mounted on said plunger to seal said plunger vent when said barrel vent is occluded and said plunger is retracted relative to said syringe barrel to creater a positive pressure within said second plunger element to maintain the sealing integrity of said second valve element.

12. The catheter introduction syringe of claim 9 wherein said first plunger element includes a conical alignment recess formed therein and said second centrally disposed channel includes a conical alignment to cooperatively form a catheter alignment means.

13. The catheter introduction syringe of claim 12 wherein said catheter alignment means further includes a conical recess formed in said second centrally disposed channel.

14. The catheter introduction syringe of claim 12 wherein said catheter alignment means further includes tapered alignment guide formed in said flexible resilient hollow tube adjacent said normally closed slit formed in said mid-portion thereof.

15. The catheter introduction syringe of claim 12 wherein said catheter alignment means further includes a conically shaped outer end portion of said syringe barrel.

16. A catheter introduction syringe for the introduction of a catheter or catheter guide wire into a patient's body, said catheter introduction syringe comprises a hollow syringe barrel to support a needle thereon having a plunger slidably disposed therein, said plunger comprises a first and second plunger element each including a countersunk recess to cooperatively form a valve recess to operatively house a valve assembly therein and a centrally disposed channel formed longitudinally therethrough including a first and second centrally disposed channels formed through said first and second plunger elements respectively, said first and second centrally disposed channels disposed on opposite sides of said valve assembly, said valve assembly comprises a rigid valve support element having a first and second valve seat formed on opposite ends of a centrally disposed channel formed therethrough to receive a first and second valve element respectively to cooperatively form a valve chamber therebetween, said first and second valve elements each comprises a flexible resilient valve member having a normally closed centrally disposed slit formed therein, said rigid valve support element disposed in surrounding relationship relative to said first and second valve elements to limit deflection of said first and second valve elements and to maintain the sealing integrity thereof, said valve assembly disposed in operative relationship relative to said centrally disposed channel to prevent passage of air or liquid therethrough during flushing or aspirating of said catheter introduction syringe and permit the introduction of a catheter or cathetr guide wire through said centrally disposed channel, said hollow syringe barrel and needle for introduction into the patient's body without the flow of air or liquid through said centrally disposed channel.

17. The catheter introduction syringe of claim 16 wherein each said flexible resilient valve member comprise a hollow substantially hemispheric member.

18. The catheter introduction syringe of claim 16 wherein said first plunger element includes a conical alignment recess formed therein and said rigid valve support elements includes a conical alignment recess formed adjacent said centrally disposed channel to cooperatively form a catheter alignment means.

19. The catheter introduction syringe of claim 18 wherein said catheter alignment means further includes a conical recess formed in said second centrally disposed channel.

20. The catheter introduction syringe of claim 19 wherein said catheter alignment means further includes a conically shaped outer end portion of said syringe barrel.

* * * * *

United States Patent [19]

Etherington

[11] **Patent Number: 4,660,569**

[45] **Date of Patent: Apr. 28, 1987**

[54] **VENTING, AUTOMATIC-STOPPING, ASPIRATING PLUNGERS FOR SYRINGES**

[75] Inventor: **Roger F. Etherington, Newport Beach, Calif.**

[73] Assignee: **Sealsyringe Corporation, San Diego, Calif.**

[21] Appl. No.: **827,516**

[22] Filed: **Feb. 10, 1986**

[51] **Int. Cl.**[4] **A61B 5/00**

[52] **U.S. Cl.** **128/765; 604/190**

[58] **Field of Search** 128/765, 766; 604/190, 604/218, 222, 405, 406, 187

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Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—William F. Frank

[57] **ABSTRACT**

The present invention is a syringe plunger stem with band-like sealing means on one end and fingergrip means on the opposite end and being slidably and sealably insertable into the body of a syringe to variate the volume capacity of the chamber of said syringe. In the plunger there is a capillary action view-tube, positioned in constant sealing contact with the said band-like sealing means and extending longitudinally towards said fingergrip end of said plunger. Further, an air-permeable, liquid impervious porous material is positioned in the said capillary action view-tube that is nearest the said fingergrip end of the plunger. The said capillary action view-tube communicating with and positioned between the said chamber of said syringe and the said air-permeable, liquid impervious porous material. The present invention may also provide a secondary chamber area in the plunger.

15 Claims, 11 Drawing Figures

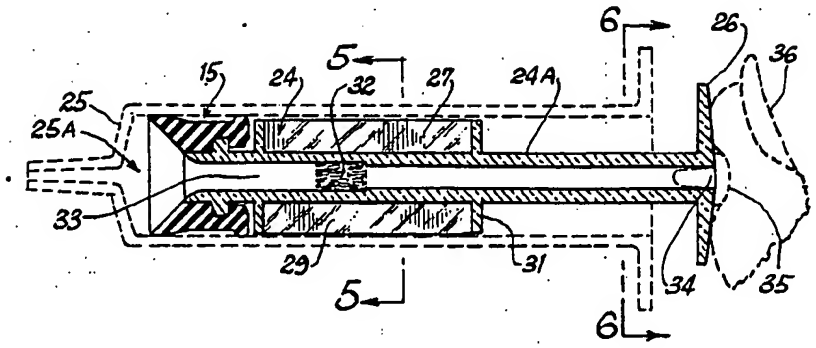
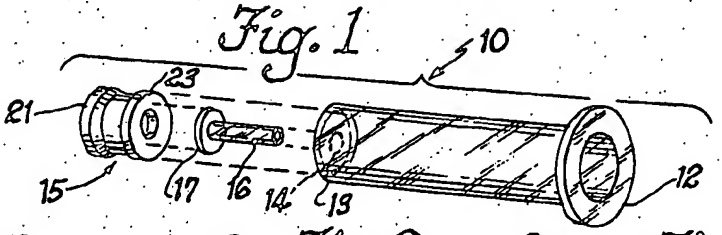


Fig. 1



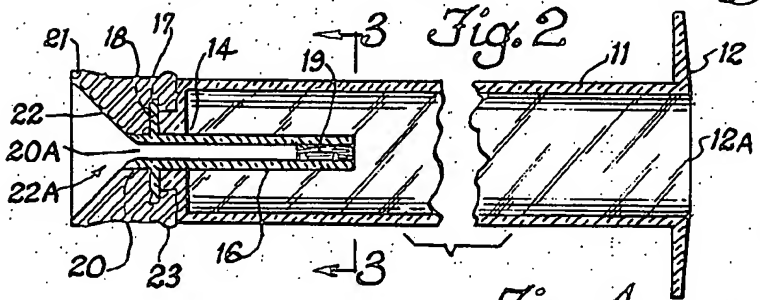


Fig. 2

Fig. 3

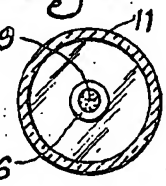


Fig. 4

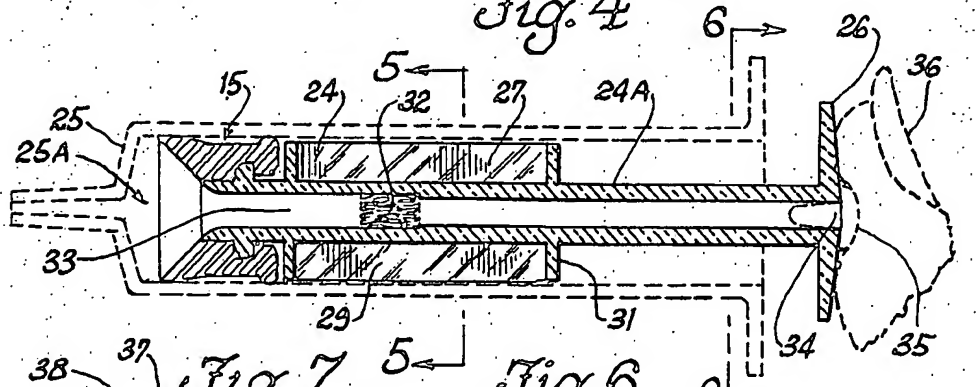


Fig. 7

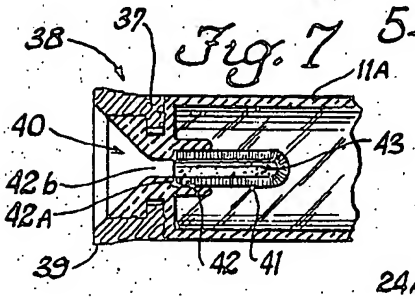


Fig. 6

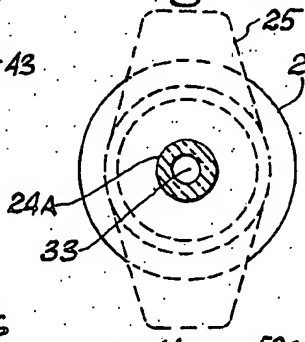


Fig. 5

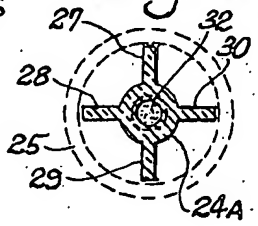


Fig. 8

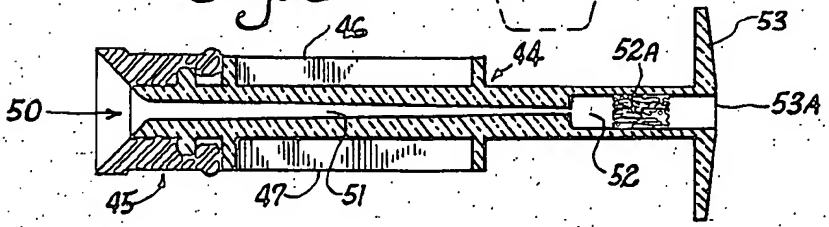


Fig. 9

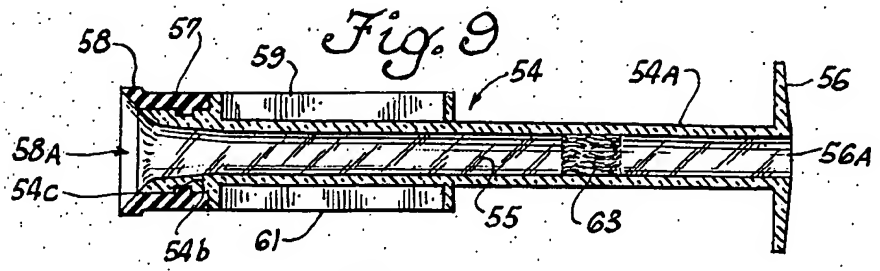


Fig. 10

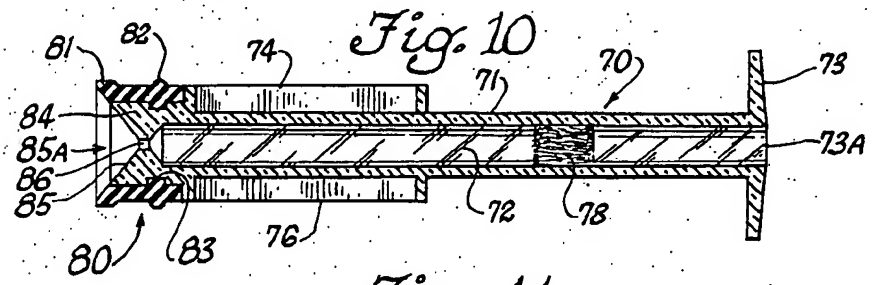
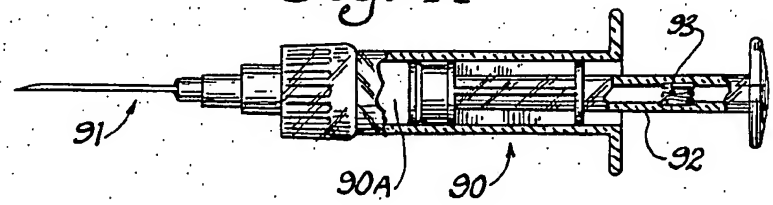


Fig. 11



VENTING, AUTOMATIC-STOPPING, ASPIRATING PLUNGERS FOR SYRINGES

FIELD OF THE INVENTION

The present invention is in the field of syringes which are used to collect arterial blood samples from patients for blood gas analysis, and more particularly, to air-venting, automatic-closing, aspirating plungers that are used in the syringes for collecting arterial blood gas samples.

BACKGROUND OF THE INVENTION AND PRIOR ART

Syringes with air-venting, automatic-stopping, aspirating plungers, hereinafter referred to as vented plungers, are typically used for collecting arterial blood gas samples. Such syringes generally utilize a dry form of heparin (anti-coagulant) for preserving the collected blood sample. Since the dry heparin occupys only a small portion of the space in the chamber of the syringe, the remainder of the space between the plunger end and the end of the syringe body is filled with air. The desired objective is for all of the air in the syringe body to be forced through the vented plunger and out of the syringe by the systolic pressure of the incoming blood. These vented plunger syringes are used not only for the collection of the sample but are also used for transporting the collected sample to the laboratory. For accurate analysis of the gas contents of the blood sample, it is important that all air-bubbles be expelled from the syringe.

Currently known vented plungers generally function in the following manner: they are slidably positioned within the syringe body to variate the capacity of the chamber in the syringe body to the desired volume, and they incorporate an automatic-closing air vent, by means of an air-permeable porous material positioned in the plunger, said porous material having microscopic pores which allows the air in the syringe to flow out of the syringe body until the material becomes wet from the incoming blood sample. These porous materials which permit air to pass through, but do not allow liquids to pass through, are well known in the art. It is important to note that after these porous materials become wet, they no longer permit air to pass through the porous material.

Additionally, some vented plungers include the feature of being able to alternatively aspirate the blood into the syringe. This aspirating feature is generally accomplished by some digital means or a plug which fits over the hole at the end of the plunger stem to close off the reverse flow of air through such hole into the chamber of the syringe. Thus, as an alternative, when difficulties are experienced in getting the blood to fill the chamber of the syringe freely under its own pressure, the vented plunger can be manually retracted to help aspirate the blood into the syringe.

There are some problems with currently known vented plungers. As examples, some have limited venting surface area, such as only three small vent holes across the entire front face of the plunger. Consequently, if the syringe is not held such that at least one vent hole is at the top position on the periphery of the plunger tip, air-bubbles may be trapped in the syringe. Some vented plungers have insufficient venting surface which restricts the volume of air flow, thereby resulting in longer fill times and greater patient trauma and discomfort. Other vented plungers have utilized a thin, film membrane of a porous material providing greater venting surface area, but which may occasionally rupture from the pressure or from the vacuum forces which are developed when the plunger is pushed in and out prior to use. Other vented plungers have tortuous, indirect air paths from the blood collecting chamber to the air-permeable material which can trap air-bubbles.

There are also vented plungers which have the air-permeable material positioned in close proximity to the front end of the plunger. Since the blood is pulsating into the syringe body, this can result in the blood splashing onto the surface of this material and closing of the air-permeable character of the material before all the air has been expelled. The fact that the syringes may not be held in a vertical position while the blood sample is being collected, but are held at a 45 degree or less oblique angle, further increases the possibility of splashing blood sealing the surface of the air-permeable material prematurely.

Another problem is that as the blood enters into the syringe, the head of that column of blood comes in contact with any air in the syringe. This makes the blood sample subject to artificial oxygenation which can cause erroneous readings on the blood sample. This condition is compounded by the pulsating wave action of the incoming blood, causing turbulent mixing of the air into the blood. When this small portion of oxygenated blood is allowed to mix with the main portion of the blood sample that is to be used for analysis, test determinations can be altered.

Other problems include the inability to see exactly when the the filling process has been completed so that the needle can be expeditiously removed from the patient. Also, the inability to visually ascertain that all air bubbles have been expelled in an inherent deficiency in some designs of the prior art. Consequently, the inability to see any air bubbles may give the operator a false sense of security. Such air bubbles which cannot be seen may remain in the syringe and may distort test determinations. The capability to precisely and accurately ascertain when the filling process has been completed and that all air bubbles have been expelled is essential to the quality of the sample to provide meaningful test determinations and to the well being of the patient.

SUMMARY OF THE PRESENT INVENTION

The present invention is a plunger barrel with sealing means on one end forming a first blood receiving chamber within a syringe body and fingergrip means on the opposite end which is slidably insertable into the body of a syringe to variate the volume capacity of the chamber of said syringe body in response to the systolic blood pressure and which has a capillary action view-tube within the plunger stem of a smaller diameter than the inside diameter of the syringe body, said capillary action view-tube being positioned in constant sealing contact with the said sealing means and in communication with the said chamber and extending longitudinally towards said fingergrip end of said plunger within said plunger barrel. The view-tube further has an air-permeable, liquid impermeable porous material positioned in the portion of the view-tube which is nearest the said fingergrip end of the plunger barrel.

In an alternative embodiment, the present invention may also provide a secondary chamber area in the

plunger which is separated from the first chamber of the syringe body by a passageway of reduced diameter.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is its basic inventive concept and alternative embodiments is disclosed in the illustrative accompanying drawings which are to be understood as non-restrictive in the application of the invention.

FIG. 1 is an exploded perspective view of the basic concept of the present invention.

FIG. 2 is a cross-sectional longitudinal axis view of the invention shown in FIG. 1.

FIG. 3 is a cross-sectional view of the basic present invention along the plane 3—3 in FIG. 2.

FIG. 4 is a cross-sectional view of a first alternate embodiment of the present invention.

FIG. 5 is a cross-sectional view of the alternate embodiment of the present invention along the plane 5—5 of FIG. 4.

FIG. 6 is a cross-sectional view of the alternate embodiment of the present invention along the plane 6—6 in FIG. 4.

FIG. 7 is a partial cross-sectional view of the second alternative embodiment of the present invention.

FIG. 8 is a cross-sectional view of a third embodiment of the present invention.

FIG. 9 is a cross-sectional axial view of a fourth embodiment of the present invention.

FIG. 10 is a cross-sectional axial view of a fifth embodiment of the present invention.

FIG. 11 is a partial cross-sectional axial view of the present invention in all of its embodiments shown inserted into a syringe as disclosed in U.S. Pat. No. 4,320,770.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

With reference to FIGS. 1-3, the basic concept of the present invention can be seen to comprise a plunger stem 10 which, in turn, comprises a transparent barrel 11 which is a hollow cylindrical tube having a finger grip end 12 with opening 12*a* and an opposing end 13 with an apertured opening 14. The opposing end 13 has secured thereto a sealing means 15 of resilient composition. Contained within the sealing means 15 and extending inwardly of said barrel through said apertured opening 14 is a cylindrical capillary action view tube 16 having a view-through transparency for observation of any fluid therein. The cylindrical tube 16 contains at a spaced distance from its said juncture with said sealing means a plug 19 of an air-permeable, liquid impermeable material. The disk-like base 17, seen in FIGS. 1 and 2, is fitted in a matching annular recess 18 in sealing means 15 and abutts a cylindrical extension 20 surrounding the apertured opening 14 of barrel 11. Sealing means 15 comprises a circular, primary and very flexible sealing bead 21 having a conical inwardly extending interior surface 22 which forms the primary chamber 22*a* with an opening 20*a* axially mating with the cylindrical tube 16 for receipt of blood from a patient. Spaced rearwardly from the primary sealing bead 21 and circumferentially surrounding the forward extension 20 of the tube 16 is a second sealing bead 23 integral with sealing means 15. While bead 23 is shown as an arcuately contured ring, it may have a knife-like terminus.

Refering now to FIG. 4–6, an alternative plunger 24 of the present invention is shown in a syringe body 25 which is seen in phantom lines forming the blood receiving chamber 25*a*, the plunger 24 comprises a hollow transparent cylindrical barrel stem 24*a* having a markedly reduced diameter, as contrasted with barrel stem 10 in FIGS. 1-3, forming a capillary viewing tube 33 terminating at its exterior end in the same conventional finger grip portion 26 as fingergrip 12 in FIG. 2 and terminating at its interior end in a sealing means 15 substantially identical to that shown in FIGS. 1 and 2. The barrel stem 24*a* seen in FIGS. 4 and 5 differs from the barrel stem 11 in FIGS. 1 and 2 in that, to support the barrel stem 24*a* within the syringe body 25, the portion of the barrel stem 24*a* extending outwardly from sealing means 15 carries four radially extending arms 27, 28, 29 and 30, which terminate in disk 31 from which barrel stem 24*a* extends outwardly to fingergrip 26. Within barrel stem 24*a* there is a plug 32 of air-permeable, liquid-impermeable material. As seen in FIG. 4, the interior cylindrical channel 33 of barrel stem 24*a* can be closed off at the exit opening 34 by selectively using a plug 35, seen in phantom lines, or by the placement of a finger 36, shown in phantom lines, if it becomes necessary to provide manual aspiration, i.e., drawing the plunger barrel stem 24*a* outwardly of syringe 25 to increase the flow of blood from the patient.

Referring now to FIG. 7, there is shown a tubular plunger barrel 11*a*, substantially identical to that in FIGS. 1 and 2, containing at its interior end face 37 a sealing means 38 having a single sealing bead 39 of a more or less knife-like edge providing a conical blood receiving chamber 40. In lieu of the axially outwardly extending portion 16 or 24*a*, as seen in FIGS. 2 and 4, there is a cylindrical hollow, closed end tube 41 forming the capillary action tube 43, which is of an air-permeable, liquid impermeable material securely held within cylindrical recess 42 of the interior end 42*a* of barrel 11*a* which mates with aperture 42*b* in blood receiving chamber 40.

With reference to FIG. 8, there is shown a plunger 44 having a hollow barrel 44*a* similar to barrel 24*a* in FIG. 4 and, sealing means 45 generally similar to that in FIGS. 2 & 4 and four extending arms 46 and 47 (extending arms 48 and 49 not being visible but substantially identical to arms 28 & 30 in FIG. 5). The sealing means 45 provides a first receiving chamber 50. Barrel 44a has an axial interior channel 51 forming a capillary action view tube which decreasingly tapers from first chamber 50 to a secondary cylindrical chamber 52 which terminates in a cylindrical fingergrip disk 53. Within chamber 52 is a plug 52*a* of air-permeable, liquid impermeable material.

In FIG. 9 there is shown a plunger 54 incorporating the basic concept of the present invention in which the plunger has a hollow cylindrical barrel stem 54*a* having an equally cylindrical bore 55 terminating at its outer end in a hollow finger grip 56 and a sealing means 57 received by recess 54*b* in the interior end 54*c* of barrel 54*a* with a single very flexible sealing lip 58 forming blood receiving chamber 58*a*. Barrel 54*a* has on the portion of its surface extending outwardly of sealing means 57 four radially extending ribs 59–61, (ribs 60 & 62 not seen). Barrel 54*a* contains within bore 55, at a distance between the outward ends of ribs 59–62 a plug 63 of an air-permeable liquid impermeable material.

In FIG. 10 there is seen a hollow cylindrical plunger 70 having a barrel stem 71 of a reduced cylindrical diameter similar to the barrel stem of the plungers seen in FIGS. 4, 8 and 9. Barrel 71 contains a hollow cylin-

drical passageway 72 which terminates at its outer end in a hollow finger grip 73. The barrel 71 carries the four radially extending arms 74–77 (arms 75 & 77 not visible) as previously described with reference to FIG. 5. Positioned between the exterior ends of arms 74–77 and finger grip 73 is plug 78 of an air-permeable, liquid impervious material substantially identical to plugs 19, 32, 52*a*, 63, 78 and 93. The interior end of barrel 71 carries a sealing means 80 which is substantially identical to sealing means 15 and 45, in that it has a first sealing bead 81 and a barrel supported secondary sealing bead 82 secured within recess 83 in the interior end portion of barrel 71. The interior end of plunger 70 differs from that shown in FIGS. 2, 4 and 8 in that it is formed as a basically cylindrical unit 84 in which its interior portion comprises an interiorly extending conical recess 85 forming a first blood receiving chamber 85*a* and having an opening 86 of reduced size which communicates with passageway 72, creating in essence a second chamber as in FIG. 8.

FIG. 11 shows a sealable syringe body 90 with attached catheter 91, but more particularly a sealable syringe body such as disclosed in U.S. Pat. No. 4,320,770, as compared to the standard syringe barrel 25 shown in phantom in FIG. 4. The sealable syringe body 90 forms the first blood receiving chamber 90*a*. The plunger 92 is one of those shown in FIGS. 4, 8, 9 or 10. It can be seen in this embodiment that it is similar to FIGS. 8, 9 and 10 in that the view tube area adjacent the plug 93 would be visible outside the body of the syringe; wherein in the the embodiments of FIGS. 1, 2 and 4 the view tube area adjacent the plug would have to be viewed through the transparent syringe barrel.

The present invention is a vented plunger which provides a solution to all of the aforementioned problems in a manner heretofore unknown. The present invention provides venting capability across the entire front face of the plunger. The present invention provides a non-rupturable porous material of adequate surface area for effective expulsion of the air in the syringe. Use of the plungers 10, 24, 44, 54, and 70 provides the capability to, alternatively, aspirate the blood sample into the syringe. It is important to understand that the band-like sealing means 15, 38, 45, 57 and 80 at the end of the barrel stems 11, 24*a*, 44*a* 54*a* and 71 are in constant sealing relationship with the barrel stems. The operator can close off air passage through the plunger and subsequently into the syringe by placing a finger over the hole 12*a*, 34, 53*a*, 56*a* and 73*a* at the end of the cylindrical plunger stem. It can be readily seen that a stopper could be utilized to plug the hole in a similar manner.

The present invention provides a novel capillary action view-tube 16, 33, 51, 55 and 72 between the primary chambers 22*a*, 25*a*, 50, 58*a* or 85*a* of the syringe and the porous material 19, 32, 52*a*, 63, and 78. The capillary action view-tube and the hollow stem will, by the distance that is created between the chamber of the syringe body and the location of the porous material and the stablizing action upon the pulsating turbulent flow of the incoming blood, reduce the possibility of the porous material becoming wet from the pulsating blood before all the air-bubbles have been expelled. Additionally, the area directly adjacent the porous material, will be clearly visible. This visibility will let the operator know precisely the moment the syringe body has finished filling and if all the air-bubbles have been effectively expelled. As may occasionally happen with all arterial blood gas syringes, if all the air-bubbles have not been expelled, the operator can take appropriate steps to manually expell them. It would be agreed to by many that air-bubbles may be inherent to this procedure. Many venting plungers of the prior art, by their own design, make it difficult to see retained air-bubbles. The present invention was developed with the concept that it is preferable for the operator to see the air-bubbles and deal with them accordingly, rather than not to be able to see them and possibly compromise the accuracy and meaningfulness of the test results.

Further, the stabilizing action of the capillary view-tube will serve to baffle the pulsating wave action of the incoming blood, thereby reducing the mixing of air into the blood sample. The small portion of blood that may have experienced oxygenation by the air within the syringe body will be in the capillary action tube area, separated away from the main portion of blood which will be utilized for anaylsis. It is a requirement of arterial blood gas samples that they be transported to the lab for analysis as quickly as possible. Therefore, diffusion of the oxygen in the small oxygenated portion into the major sample portion is further minimized or totally eliminated.

In an embodiment shown in FIG. 8, the plunger may provide a secondary chamber 52 in the plunger, which is separated from the primary or first chamber 50 of the syringe by an elongated reduced diameter passageway 51, and in which secondary chamber 52 there is positioned an air-permeable, liquid impermeable porous material 52*a*. This secondary chamber 52 may provide additional space for oxygenated blood and air-bubbles in an area which would be further separated from the main blood sample. Also, this reduced diameter passageway 51 would serve to further baffle the fluid flow and to separate the columns of blood.

In the embodiment in FIG. 7, the capillary action tube 41 of an air-permeable, liquid impermeable porous material would provide venting capability through all the tubular wall surfaces, as well as through the end of the tube. This additional venting surface would minimize the possibility of air-bubbles getting trapped within the tube.

The use of a sealing means with a single sealing bead 39 as shown in FIG. 7 and 58 in FIG. 9 which have minimal drag resistance and can be carried by plungers 10, 24, 11*a*, 44, 54 and 70 in FIGS. 2, 4, 7, 8, 9 and 10 could be utilized in conjunction with a novel method for collecting arterial blood gas samples which is described as follows:

Instead of pre-setting the plunger within the syringe body to the desired volume capacity, the plunger would be set at the full-forward minimum capacity position,

The arterial puncture would be accomplished in the usual manner, and as the blood entered into the syringe under its own systolic pressure, all the air in the syringe would be forced out until the porous material became wet from the incoming blood;

At this point, the systolic pressure of the blood will start driving the plunger rearwardly until the operator stops the plunger at the desired volume, or until the plunger hits a pre-determined mechanical stop.

The arterial puncture is terminated and the collected sample is treated in the usual manner.

The advantages of this novel specimen collection method include:

When standard vented syringe plungers are pre-set for a volume capacity of 3 cc's, and for whatever rea-

sons such as collasped arteries, low blood pressure or difficulties in finding the artery with the needle, the actual collected sample is only 1 to 2 cc, there will of course be 1 or 2 cc of air remaining in the syringe. Typically, if the operator continues to try to obtain a greater amount of sample by aspirating the blood into the syringe, first, the incoming blood may become mixed with the air that is in the syringe; secondly, the decompression (vacuum) force of that aspiration may alter the oxygen tension of the blood sample; and thirdly, that remaining air is further mixed into the sample when the operator takes action to manually expell the air.

With the light drag embodiment of the present vented plunger, when it is pre-set at its forwardmost position, the volume capacity and therefore the initial amount of air in the syringe will be minimal. In a normal collection operation, wherein the full amount of sample is collected, after the initial small portion of blood voids the syringe of all air, the major portion of the blood that will be utilized for test purposes, will be filling into a syringe that is free of air. In such situations that a sample volume shortfall occurs, aspiration of the remainder of the sample may also be accomplished with no air in the syringe. Under any circumstances, there is less air in the syringe and less chance of unwanted oxygenation of the blood sample with this combination venting and light drag plunger method.

The present invention may be summarized as a plunger used in a syringe body for blood gas collection in which the plunger contains a transparent, viewing chamber having an air-permeable, blood or liquid impervious plug positioned near its exterior end and sealing means on the interior of said plunger which prevent the escape of the blood around or through its periphery, while in some of its embodiments, eliminating or substantially reducing the resistance to rearward movement of the plunger by the systolic pressure of the blood. Those of skill in the related art will recognize that the changes in the exterior form or shape of the plunger barrel will come within the scope of the present invention as recited in the following claims.

What is claimed is:

1. A venting, automatic-stopping, aspirating plunger for syringes used in collection of blood, comprising:

an elongated hollow plunger barrel stem with band-like sealing means on its interior end within the syringe body forming a chamber communicating with said hollow stem and a fingergrip means on the exterior end and being slidably insertable into the body of a syringe to variate the volume capacity of the said chamber of said syringe while maintaining a sealing relationship between said sealing means of the plunger and internal surfaces of the syringe body;

a hollow capillary action view-tube formed within the said hollow plunger barrel stem, said capillary action view-tube positioned in constant sealing contact with the said band-like sealing means and extending co-axially with the longitudinal axis of said stem towards said fingergrip end of said plunger, and;

an air-permeable porous material positioned in the said hollow capillary action view-tube nearest said fingergrip end of the plunger, said porous material characterized as having microscopic pores within for permitting air to permeate therethrough but which will not permit the passage of blood.

2. The apparatus according to claim 1, wherein the said band-like sealing means has two axially spaced annular sealing beads making said sealing relationship.

3. The apparatus according to claim 1, wherein the said band-like sealing means has only one annular sealing bead making said sealing relationship to provide minimized frictional drag thereby requiring less force to slide the said plunger within the said syringe barrel.

4. The apparatus according to claim 1, wherein the said capillary action view-tube is in direct open communication with the said chamber of said syringe.

5. The apparatus according to claim 1, wherein there is a passageway of reduced diameter positioned between the said chamber of said syringe to a secondary chamber in the said hollow plunger stem, said secondary chamber containing said air-permeable porous material and being adjacent said grip means, said secondary chamber having an interior diameter greater than the diameter of said passageway.

6. A venting, automatic-stopping, aspirating plunger for syringes, comprising:

a hollow plunger barrel stem with band-like sealing means secured in a annular recess on one end and fingergrip means on the opposite end, said sealing means forming with said one end of said stem an interiorly extending conical chamber, said stem being slidably insertable into the body of a syringe to variate the volume capacity of said syringe while maintaining a sealing relationship between the peripheral surfaces of the sealing means and the internal surfaces of the syringe barrel, said chamber having an aperture in said one end of said stem, and;

a capillary action tube within the said hollow plunger barrel stem, said capillary action tube being formed entirely of an air-permeable porous material and positioned in constant sealing contact with a recess in the interior end of the said plunger barrel and the said band-like sealing means in communication with siad aperture and extending axially of said barrel from said chamber towards said fingergrip end of said plunger; said porous material characterized as being comprised of microscopic pores for permitting air to permeate therethrough but which will not permit the passage of blood.

7. Method for the collecting of an arterial blood sample for blood gas analysis into a hypodermic syringe body which has been pre-heparinized with a dry form of anti-coagulant and in which syringe body there is a hollow barrel-like plunger inserted into the barrel of said syringe for variating the volume capacity of said syringe, wherein said plunger incorporates a sealing means on its interior end within said syringe body which has at least one annular sealing bead establishing sealing relationship between the external peripheral surfaces of said sealing means and internal surfaces of the syringe body, thereby eliminating or substantially reducing the frictional drag and minimizing the amount of force required to move the said plunger within the said syringe body; the said sealing means forming an interiorly extending conical chamber to receive said sample, the said plunger further having a tube within said plunger barrel in communication with said chamber and extending outwardly toward the exterior end of said plunger with an air-permeable porous material within said tube which allows the venting of air into and out of the said hollow plunger barrel but which material does not allow the passage of blood, comprising the

steps of pre-setting the said plunger at its full forward minimum capacity position; placing the said syringe in communication with a source of blood from which the said sample is to be taken; permitting the systolic pressure of the blood to fill the said syringe with said blood sample and forcing the air which was in the said chamber of said syringe body out through the said porous material; continuing to fill the said syringe body with the said blood sample by the said systolic pressure thereby pushing the said plunger rearwardly until the desired volume of blood sample is collected, and removing the said syringe with collected said arterial blood sample away from the said source of blood.

8. The method according to claim 7 wherein the flow of blood into the syringe body is terminated by visual sighting of the pre-determined quantity.

9. The method according to claim 7 wherein the flow of blood into the syringe body is terminated by the plunger barrel contacting a pre-determined stop.

10. An arterial blood gas sample collecting device comprising in combination an elongated self-sealing syringe and a venting, automatic-stopping, aspirating plunger wherein said syringe comprises:

a hollow, cylindrical body having an open end and an opposing end with an aperture therethrough eccentrically positioned with reference to the longitudinal axis of the body, a rotatable sealing cap for said closed end, said cap having a depending skirt encompassing the closed end of said body with means on said cap engaging means on the external surface of said syringe body to limit rotational movement of said cap which has an aperture in its external end extending therethrough parallel to the longitudinal axis of said cap, which aperture has an eccentricity relative to said axis substantially identical to the eccentricity of the aperture in said closed end, said closed end of said syringe body having an O-ring seal around said closed end aperture extending above said closed end outer surface into contact with an inner surface of said cap and providing a sealed bearing surface for said cap during rotation thereof between a position when both of said apertures are in communication and a position in which said apertures are not in communication;

wherein said plunger comprises:

an elongated hollow plunger barrel stem with band-like sealing means on its interior end within said syringe body forming a chamber communicating with said hollow stem and fingergrip means on the exterior end and being slidably insertable into the body of a syringe to variate the volume capacity of the chamber of said syringe while maintaining a sealing relationship between said sealing means of the plunger and internal surfaces of the syringe body;

a hollow capillary action view-tube formed within the said hollow plunger barrel stem, said capillary action view-tube positioned in constant sealing contact with the sand band-like sealing means and extending co-axially with the longitudinal axis of said stem towards said fingergrip end of said plunger, and;

an air-permeable porous material positioned in the said hollow capillary action view-tube nearest the said fingergrip end of the plunger, said porous material characterized as having microscopic pores within for permitting air to permeate therethrough but which will not permit the passage of blood.

11. The apparatus according to claim 10, wherein the said band-like sealing means has two axially spaced annular sealing beads making said sealing relationship.

12. The apparatus according to claim 10, wherein the said band-like sealing means has only one annular sealing bead making said sealing relationship to provide minimized frictional drag thereby requiring less force to slide the said plunger within the said syring barrel.

13. The apparatus according to claim 10, wherein the said capillary action view-tube is in direct open communication with the said chamber of said syringe.

14. The apparatus according to claim 10, wherein there is a passageway of reduced diameter positioned between the said chamber of said syringe to a secondary chamber in the said hollow plunger stem, said secondary chamber containing said air-permeable porous material and being adjacent said grip means, said secondary chamber having an interior diameter greater than the diameter of said passageway.

15. The apparatus according to claim 10 wherein said plunger comprises:

a hollow plunger barrel stem with band-like sealing means secured in a annular recess on one end and fingergrip means on the opposite end, said sealing means forming with said one end of said stem an interiorly extending conical chamber and being slidably insertable into the body of a syringe to variate the volume capacity of said syringe while maintaining a sealing relationship between the peripheral surfaces of the sealing means and the internal surfaces of the syringe barrel, said chamber having an sperture in said one end of said stem, and;

a capillary action tube within the said hollow plunger stem, said capillary action tube being formed entirely of an air-permeable porous material and positioned in constant sealing contact with a recess in the interior end of the said plunger barrel and the said band-like sealing means in communication with said aperture and extending axially of said barrel from said chamber towards said fingergrip end of said plunger; said porous material characterized as being comprised of microscopic bores for permitting air to permeate therethrough but which will not permit the passage of blood.

* * * * *

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United States Patent [19]

Pozzi et al.

[11] Patent Number: 5,176,639

[45] Date of Patent: Jan. 5, 1993

[54] SINGLE-INJECTION SYRINGE

[75] Inventors: Didier Pozzi, 8, rue Paul-Houette; Jean-Pierre Pozzi, 6, allée des Tilleuls, both of F-92190 Meudon, France

[73] Assignees: Jean-Edouard Clotteau, Paris; Didier Pozzi; Jean-Pierre Pozzi, both of Meudon, all of France

[21] Appl. No.: 477,804

[22] PCT Filed: Jun. 1, 1989

[86] PCT No.: PCT/FR89/00270

§ 371 Date: Feb. 2, 1990

§ 102(e) Date: Feb. 2, 1990

[87] PCT Pub. No.: WO89/11886

PCT Pub. Date: Dec. 14, 1989

[30] Foreign Application Priority Data

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Dec. 30, 1988 [FR] France 88 17474

[51] Int. Cl.[5] A61M 5/315

[52] U.S. Cl. 604/110; 604/228; 604/236

[58] Field of Search 604/90, 110, 187, 203, 604/205, 226, 228, 229, 236-238, 218

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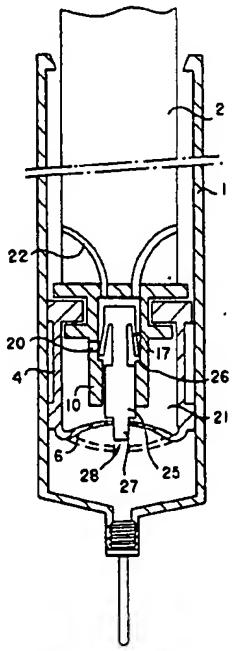
Primary Examiner—John D. Yasko
Assistant Examiner—Anthony Gutowski
Attorney, Agent, or Firm—Armstrong & Kubovcik

[57] ABSTRACT

Inside a syringe (1) slides a plunger (2) which bears a joint (4) sliding sealingly over the internal wall of the syringe. The flexible membrane (6) of the joint (4) fixed to the end of the plunger (2) bears a closing component (25, 27) which follows the movement of deformation or displacement of the membrane through the effect of the pressure built up during the injection stage, but which is retained by immobilizing strips (17) in a position in which it opens the orifice, breaking the seal between the top and the bottom of the joint, as soon as the membrane returns to its initial position.

5 Claims, 5 Drawing Sheets



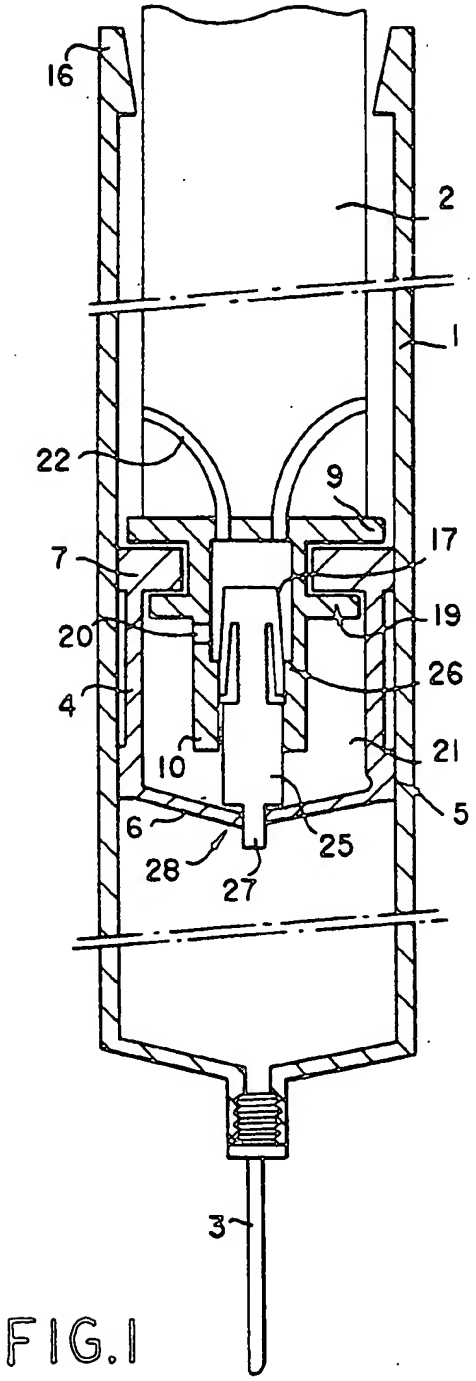

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FIG.1

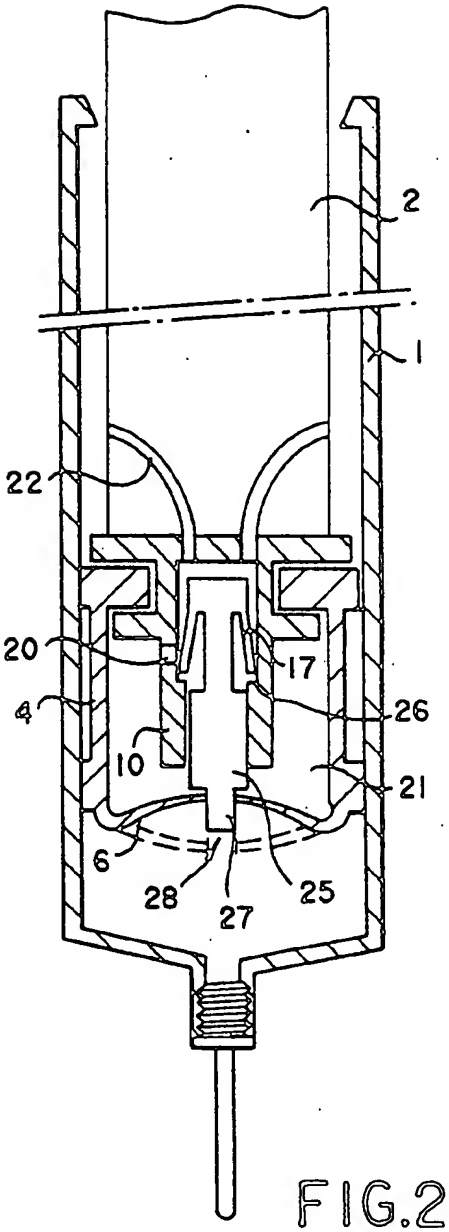
2
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FIG.2

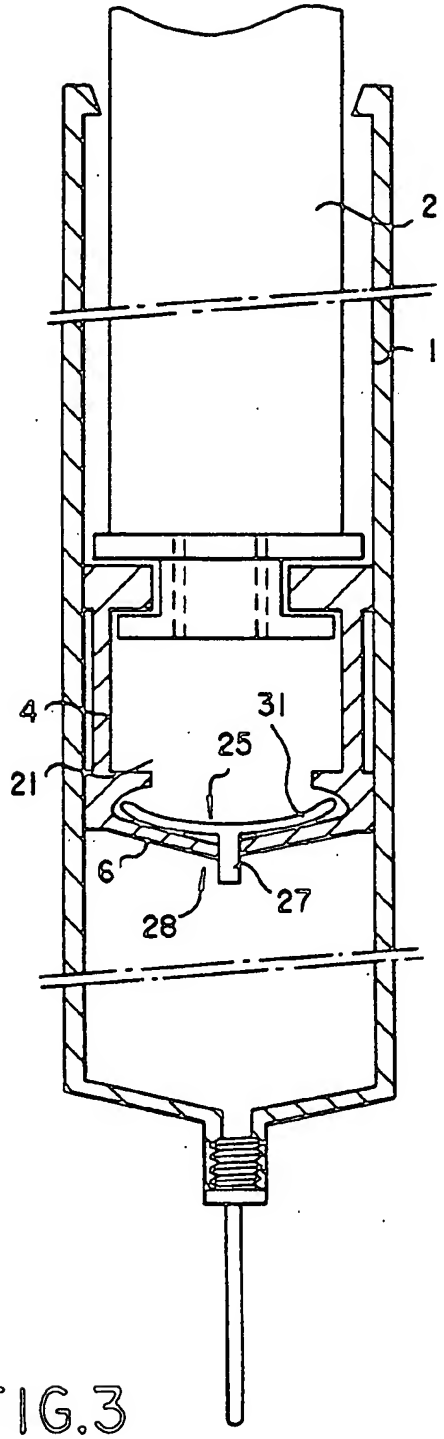

FIG.3

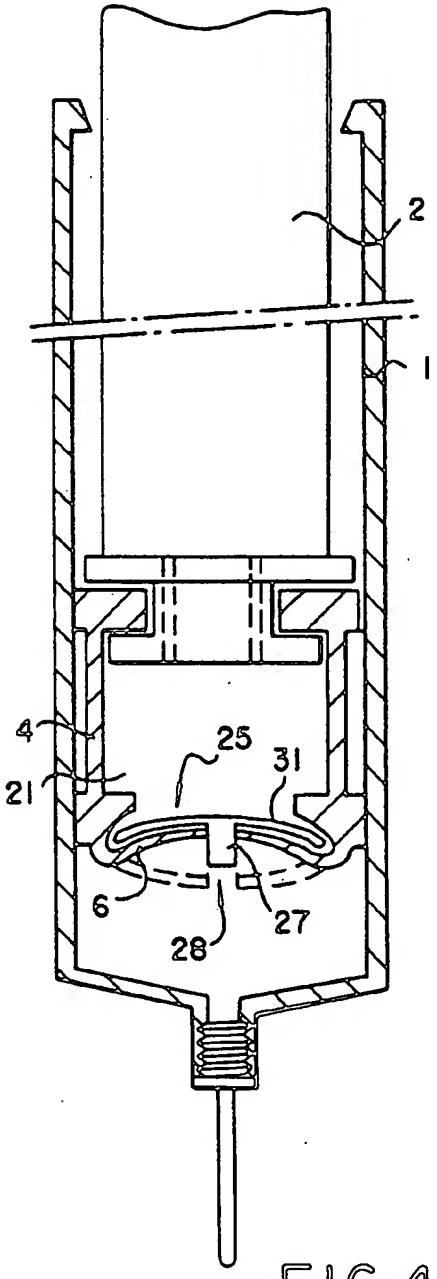

FIG.4

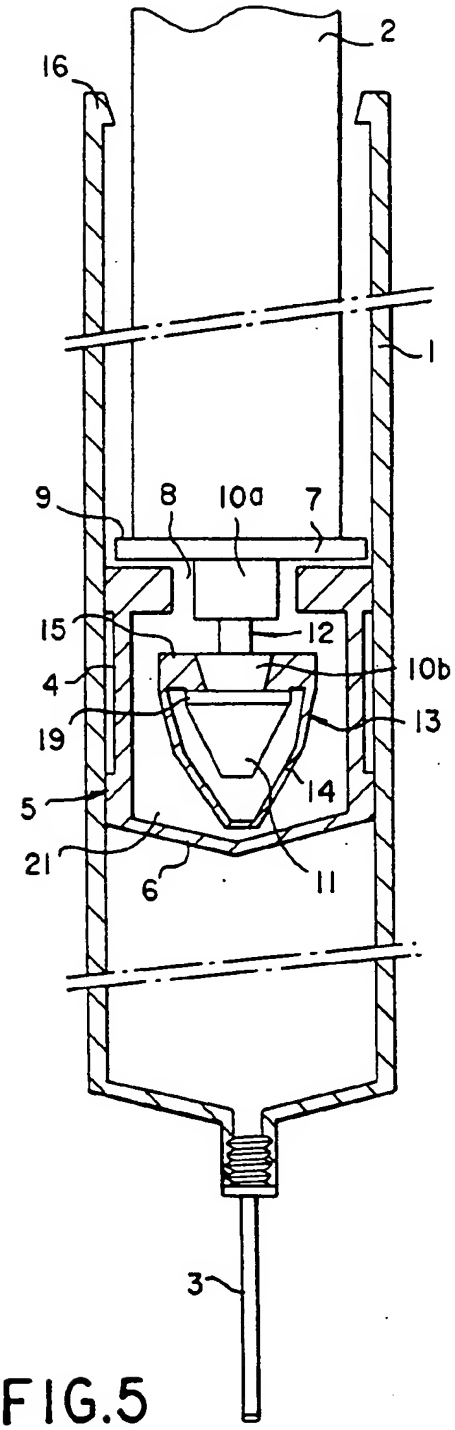
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FIG.5

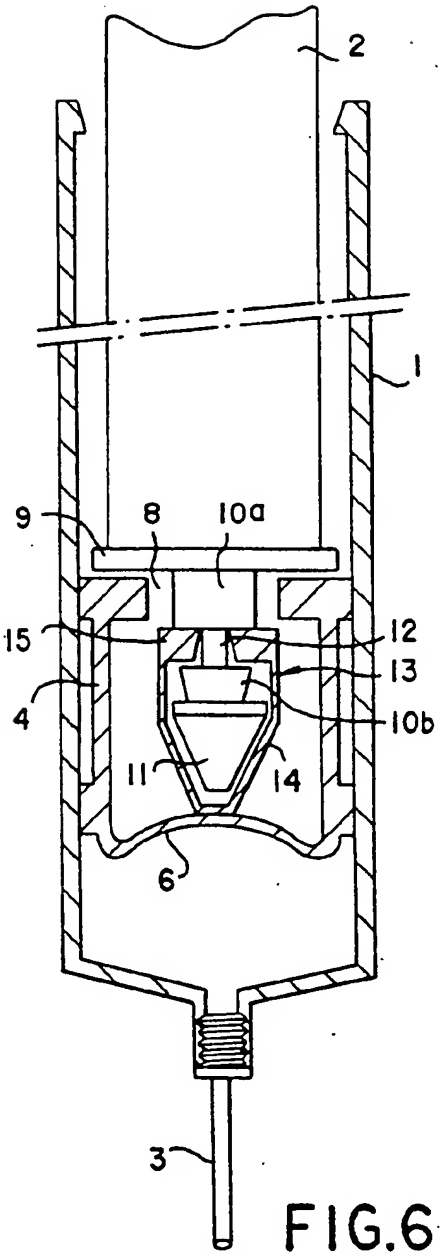
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FIG.6

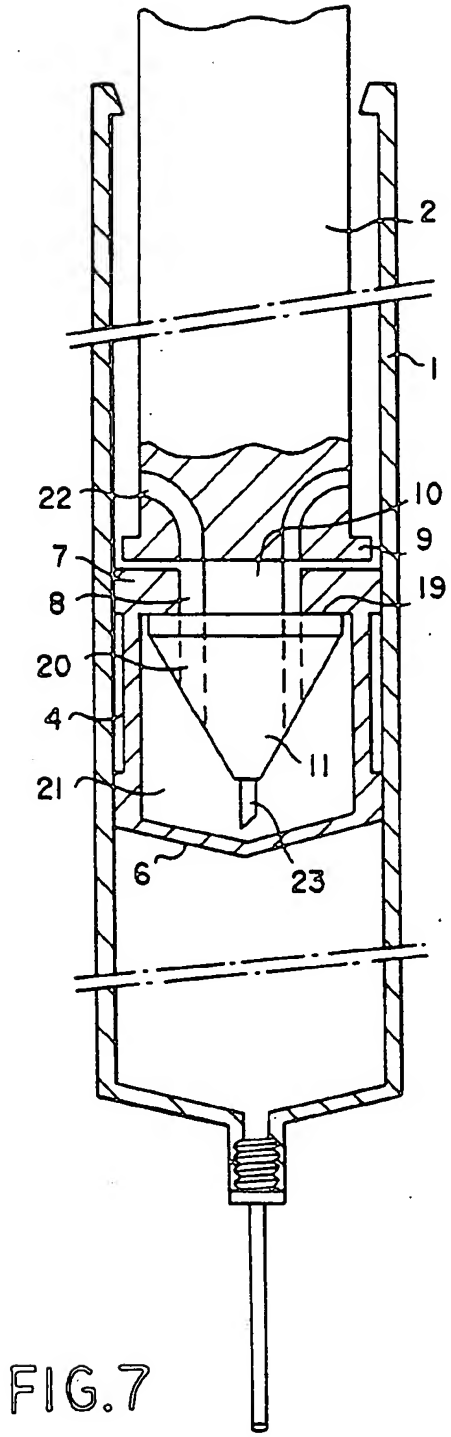

FIG.7

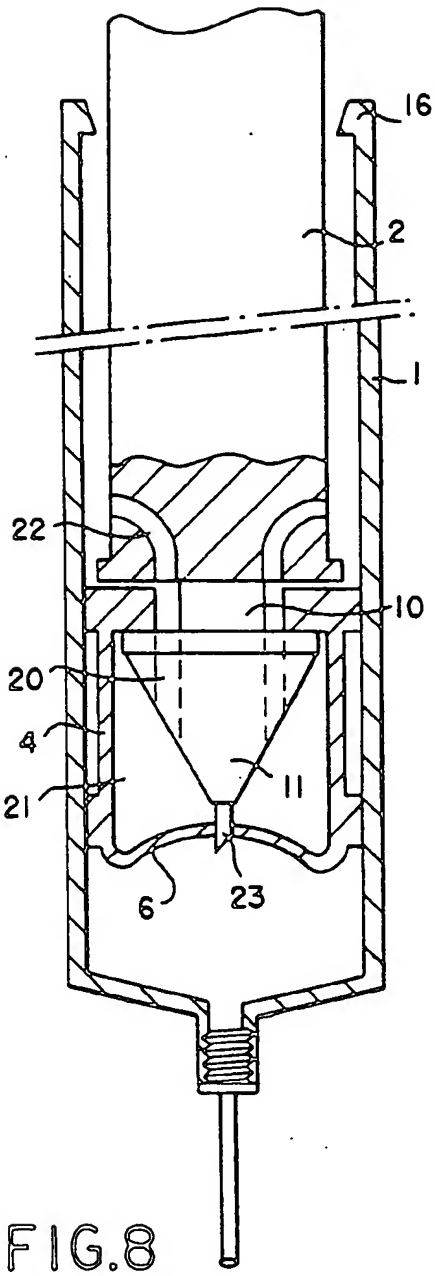

FIG.8

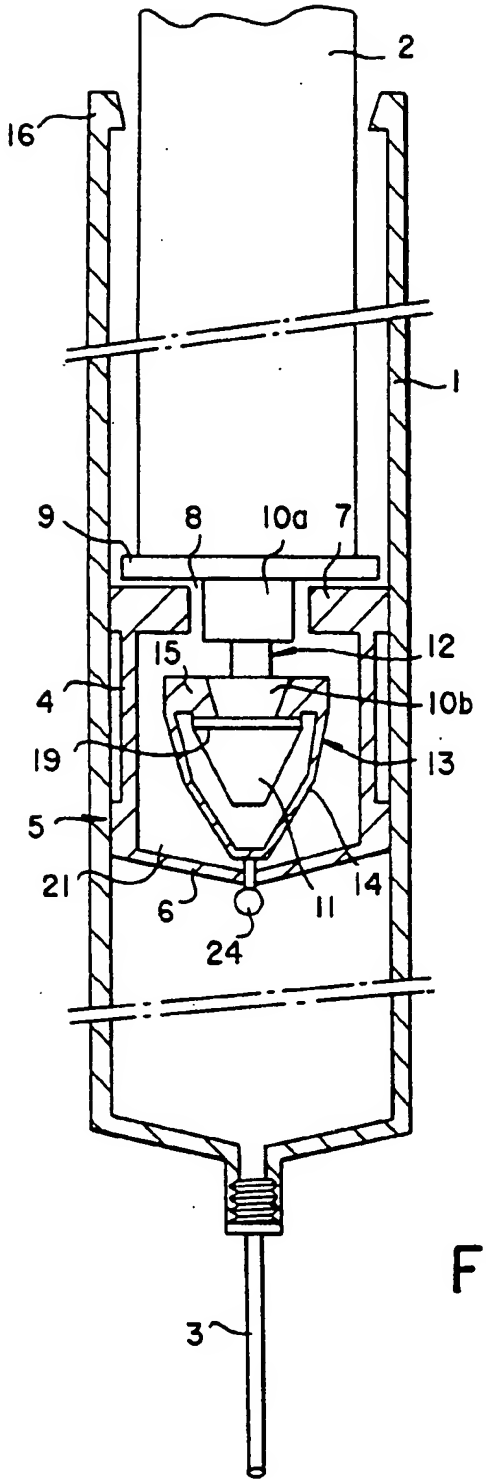

FIG.9

SINGLE-INJECTION SYRINGE

FIELD OF THE INVENTION

The present invention relates to a disposable syringe, that is one that can be used only once, and relates more precisely to a device that renders the sealing joint inoperative after a first injection.

BACKGROUND OF THE INVENTION

In the field of therapeutics, the use of syringes for injecting fluids into tissues or natural cavities in the body is extremely widespread. A syringe is known to be composed essentially of a cylindrical barrel in which a plunger slides, a body whose base bears a nozzle of a suitable shape to which can be fitted a hollow needle, for example a needle made of steel or nickel, the barrel thus forming a reservoir for the fluid to be injected. The structure or composition of the plunger can vary according to the model. It is, in any case, provided at one of its ends with a joint to ensure sealing with the barrel of the syringe and, at its other end, which is always external to the barrel of the syringe, a plunger head to facilitate its handling. This classical syringe makes it possible to perform in the habitual manner the operations required for an injection as commonly practised, that is in the first place, detaching the joint at the bottom of the syringe and then, by applying traction to the plunger to extract it from the barrel of the syringe, drawing in a certain quantity of fluid. Then, with the syringe in inverted position, that is with the needle pointing upwards, a slight pressure on the plunger causes any air remaining in the reservoir to be discharged, this operation possibly being followed by the drawing in of a complementary quantity of fluid and again the essential discharge of the air.

Before injection properly speaking, slight re-aspiration is practised after insertion for checking purposes.

There are known disposable syringes used for vaccinations which are pre-filled in the laboratory and with which it is no longer possible to draw in fluid after the injection. However, as most syringes used are not prefilled and since it has to be possible for the to and fro movements of the plunger to be performed for the operations described above, or for manipulations in an empty condition, it is not possible to adopt this system.

SUMMARY OF THE INVENTION

One object of the present invention is thus to provide a device adaptable to any syringe, which permits the performance of all the operations necessary for a complete injection and thus including the to and fro movements of the plunger or its manipulation in an empty condition as described above, but which strictly precludes re-use for a second injection, the device rendering the sealing joint inoperative after the first injection by making use of the action of the pressure exerted by the fluid, during injection, on a flexible part of the joint to detach the joint from its driving plunger, or to destroy its function as a sealing member.

The invention thus relates to a disposable syringe comprising a cylindrical syringe barrel to the base of which can be fixed different sorts of sampling and/or injection needles, as well as a plunger sliding inside the syringe barrel and whose end bears a joint the slides sealingly over the internal wall of the syringe, a syringe in which the joint comprises at least one member capable of being deformed or displaced from its position of

equilibrium through the action of the pressure exerted by the fluid contained in the syringe at the time of the injection stage, the sliding plunger being associated with the joint via components that react to the deformation or the displacement of the member and which render the joint inoperative for the purposes of refilling after the injection.

According to the special features of the invention, the joint is a hollow cylindrical component whose lower face is formed by a flexible membrane that constitutes the deformable member and which ensures sealing between the syringe barrel and the chamber inside the joint and whose annularly shaped upper portion bears against the plunger, which plunger extends, through the orifice in the annular portion of the joint, by an axial rod having a diameter less than that of the orifice and ending in a head forming a shoulder with the rod.

According to one special feature of the invention, the flexible membrane or the displaceable member has an orifice that is normally tightly closed by a closing component which follows the movement of deformation or displacement of the membrane or of the member through the effect of the pressure built up during the injection stage, but which is retained by an immobilizing device in a position in which it opens the orifice, breaking the seal between the top and bottom of the joint, as soon as the membrane or the member returns to its initial position.

DESCRIPTION OF THE DRAWINGS

Other special features and advantages of the invention will emerge as a result of reading the following description of examples of embodiments with reference to the annexed drawings, wherein:

FIG. 1 is a schematic view in elevation of an equipped syringe in a rest position;

FIG. 2 shows the same syringe during an injection stage;

FIGS. 3 and 4 show another form of embodiment, also in two positions;

FIGS. 5 and 6 show another variant of a syringe equipped with a device for detaching the joint in a rest position and in an injection position.

FIGS. 7 and 8 show a schematic elevation view of a syringe equipped with a device for perforating the joint, in a rest position and in an injection position;

FIG. 9 shows an alternative form of embodiment.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The syringe represented in FIG. 1 is composed essentially of a cylindrical syringe barrel 1 to the base of which is fixed a sampling or injection needle 3, a plunger 2 sliding inside the syringe barrel and a sealing joint 4 mounted on the end of the plunger and sliding sealingly over the internal wall of the syringe. The plunger cannot be withdrawn from the barrel of syringe 1 because of a non-return device 16 which prevents any interference with the device. The sealing joint 4 takes the form of a hollow cylindrical component whose external wall is provided with integrally moulded ribs 5, forming a seal on the internal wall of syringe barrel 1. The lower face of the joint, opposite the orifice in the syringe barrel, forms a flexible membrane 6 whose thickness is reduced in relation to the rest, a membrane which, in the position of equilibrium, is substantially horizontal and ensures sealing between the syringe bar-

rel and a chamber 21 internal to the joint. On the other side. the upper portion 7 of the annularly shaped joint. bearing against a shoulder 9 of the plunger, is thicker and is provided with a central orifice 28. The lower face of this upper portion 7 of the joint bears against a shoulder 19 projecting from a hollow cylindrical rod 10 which prolongs the plunger 2 and extends inside the joint. Joint 4 is thus made integral with the plunger 2. Inside the hollow rod 10 is placed a closing component 25, having a generally elongated shape, and whose cross-section is cylindrical or star-shaped. This component is able to move with a slight amount of clearance inside the shaft constituted by rod 10 which further bears an internal shoulder 26 delimiting within the rod a lower shaft having a smaller cross-section than the upper shaft at the annular portion 7. The shoulder could also be a boss covering or otherwise the entire circumference of the shaft. The closing component 25 ends towards the bottom in a closing head 27 which closes a small orifice 28 provided in the membrane 6. On its upper portion, closing portion 25 carries elastic strips 17 held folded back when they are applied against the internal wall of rod 10, and which play the part of a non-return member, as we shall see later. It will be noted that rod 10 is traversed by ports 20 placing the internal chamber 21 of the joint 4 in communication with the internal shaft of the rod and, thereby, via ports 22 provided in the plunger, with the syringe above the shoulder of the plunger. The position represented in the FIG. 1 corresponds to the pre-injection stage. Head 27 of the closing component 25 sealingly closes the membrane 6, following its movement.

Directly the injection stage commences. as represented in FIG. 2. Through the effect of the pressure built up. membrane 6 is deformed from the position shown in dashed lines to the position shown in solid lines. The closing component 25 follows this movement and the elastic strips 17 then escape from the lower shaft and spread out in the upper well. They will then be immobilized by the shoulder 26, making any return of the component to its initial position impossible. This non-return function only takes effect if the pressure in the reservoir has reached a predetermined maximum value, the displacement of the closing component remaining reversible for all values lower than the said pressure. Following injection, the joint 4 remains integral with the plunger but, as the deformed portion of the membrane 6 is no longer subjected to the positive pressure, it has regained its initial shape. However, the closing head 27 remains at a distance from the membrane and orifice 28 is disengaged. Chamber 21 is connected to atmosphere by the ports 22 provided in plunger 2, and by ports 20, and also communicates with the bottom of the syringe via orifice 28. The seal is thus broken between the top and the bottom of the joint. Thus, it becomes impossible to fill the injection device by drawing in fluid or through the action of a pressurized fluid, or to perform an injection.

According to another form of embodiment, not shown, it can be contemplated that the bottom 6 remains rigid but that it is the side walls of the joint 4, below its annular portion 7, that are deformed and fold at the time of the injection stage and displace the base of the joint and the closing component upwards.

According to yet another form of embodiment, not shown, the closing portion is not fitted with non-return elastic strips 17 but is stuck in the top position against the plunger by means of an adhesive or a suitable glue located on the plunger and/or the component.

FIGS. 3 and 4 show yet another form of embodiment, again in the two habitual operating stages. This time, the closing component 25 is constituted by a dome-shaped strip 31 the concavity of which is directed downwards. in the same direction as that of the undeformed membrane 6 of the joint 4 inside which it is maintained. The dome-shaped strip 31 bears in its center a closing head 27 which also cooperates with orifice 28. In the initial stage (FIG. 3), strip 31 is in a cambered position, as shown, in which orifice 28 is closed. At the time of the injection stage illustrated in FIG. 4, the positive pressure in the syringe is sufficient for deformation of the membrane 6 to push the dome-shaped strip 31 upwards. Its concavity then changes direction and it remains in this position. When the membrane regains its initial position, at the end of injection, orifice 28 is no longer closed by closing head 27 since the strip has remained cambered in the upper position. It will be noted that the friction between the head 27 and the edges of the membrane around its orifice 28 is insufficient to return dome-shaped strip 31 from the position shown in FIG. 4 to that shown in FIG. 3 merely through the traction of membrane 6 returning to its initial position.

According to another form of embodiment, not shown, the dome-shaped strip, instead of being associated with the joint 4, could be associated with a displaceable rigid member.

In the case of the variants in FIGS. 3 and 4, operation and the result obtained are the same as in the case described with reference to FIGS. 1 and 2.

The invention has been described with reference to a joint 4 that takes the form of a hollow cylindrical component whose external wall is provided with integrally moulded ribs forming a seal on the internal wall. of syringe barrel 1, and whose lower portion is a deformable membrane 6. The invention can also be considered as applying to a syringe plunger fitted with at least an added joint or profiled so as to act as a joint itself, which would be equipped with a deformable member playing the same part as that described above, or with a displaceable component instead of providing for displacement of the bottom of the joint, described earlier, through the effect of pressure.

To improve non-reutilization security yet further, it can be advantageous to provide for an area of weakness, for example at closing head 27. Any attempt to restore the closing component 25 to its initial position by traction would result in rupture between the head and the closing component.

We shall now describe, with reference to FIGS. 5 and 6, another form of embodiment in which, this time, the membrane 6 of joint 4 is no longer perforated and remains tight but contains a device that detaches the joint from the plunger.

It can be see from FIG. 5, in which the same reference numbers are used for the same components as those described in connection with FIG. 1, that axial rod 10 which extends the plunger has a portion 10*a* with a diameter substantially less than the diameter of orifice 8, at the orifice, and that the rod ends in a conical head 11 with a larger diameter forming a shoulder 19 with the rod, a conical head whose tip is orientated towards the membrane 6 of the joint, the diameter of the shoulder remaining less than the diameter of orifice 8. Rod 10 has a neck 12 between shoulder 9 and conical head 11,

the head being conical to enable the plunger to be mounted more easily on a clamp. Portion 10*b* of the rod between the neck and the conical portion has been bevelled to present a slightly conical profile, as seen from FIG. 5. An elastic clamp 13 formed by arms 14 which turn inwards by jaws 15 towards the center of the syringe is arranged inside joint 4 and caps conical head 11. It is shown spread in FIG. 5 and its jaws 15 whose ends have a conical profile corresponding to that of portion 10*b* bear against portion 10*b* of rod 10 and against the upper shoulder of the conical portion.

If a downward pressure is applied to plunger 2, shoulder 9 pushes against the upper face 7 of the joint. If, on the other hand, upward traction is applied to the plunger, starting from the position shown in FIG. 5, for example to ensure that fluid is drawn into the syringe, the jaws 15 of the clamp held apart by portion 10*b* by a distance greater than the diameter of orifice 8 abut against the annular portion 7 of the joint and enable the latter to be driven together with the plunger. The way in which the plunger and the joint are thus rendered integral permits the operations prior to injection mentioned previously.

FIG. 6 illustrates the final stage of fluid injection while the plunger 2 is descending towards the bottom of syringe 1. At that moment, the pressure of the fluid in the syringe, through the effect of the thrust of joint 4, causes deformation of the membrane 6, which bulges towards the interior of the joint 4. The membrane then bears against clamp 13, displacing it upwards until the jaws 15 escape from portion 10*b* of the rod and, as a result of the elasticity of arms 14, close up in groove 12. The spread of the clamp is then reduced to a size that is less than that of orifice 8 and it will then be appreciated that, following injection, if it is attempted to draw the plunger out of the syringe, the clamp will pass through orifice 8 and the joint will remain at the bottom of the syringe. It will be noted that, even if this detachment from the joint through withdrawal of the clamp has occurred at the start of the depression stroke of the plunger, injection will not be adversely affected thereby and will be able to continue normally thanks to the thrust of shoulder 9 against the joint. At the end of the stroke, conical head 11 of plunger 2, through its action on membrane 6, will press the latter against the bottom of the syringe, enabling all the fluid to be injected. The deformation of the joint in this final stage is of no importance since, in any case, the clamp will no longer be able to cooperate with annular portion 7 of the joint, which will remain at the bottom.

If, for any reason, the jaws of clamp 13 should fail to escape from portion 10*b* of the rod, as a result of the pressure, detachment would nonetheless occur when the clamp came into abutment through the membrane with the bottom of the syringe, at the end of the plunger travel stroke.

The clamp which can be seen in FIGS. 5 and 6 can have a profile that differs from that shown and, in particular, a lower face, from which extend arms 14, that is substantially larger, to avoid sliding on membrane 6 and to cooperate more easily therewith at the end of injection.

There will now be described yet another form of embodiment in which membrane 6 is impervious, as in the above cases, and not provided with an orifice, but in which, on the other hand, it can be perforated.

This variant is described with reference to FIGS. 7 and 8, which show that conical head 11, still integral with plunger 2 via rod 10, and housed inside joint 4, is larger in size. Its shoulder 19 in relation to the rod abuts against the annular lower portion 7 of joint 4, capping orifice 8. This annular portion 7 of the joint is thus pinched between shoulder 9 and shoulder 19; the joint and the plunger are thus rendered inseparable. As in the cases illustrated in FIGS. 5 to 6: conical head 11 is traversed by ports 20 placing the internal chamber 21 of joint 4 in communication with orifice 8. Other ports 22 are provided in the plunger itself so that there is free communication of air between chamber 21 and the syringe, above shoulder 9 of the plunger. In addition, conical head 11 is provided at its end with a point 23 orientated towards membrane 6, a point that could also be replaced by a cutting part of any shape.

In the position represented in FIG. 7, which corresponds to a stage in operations that is preliminary to injection properly speaking, membrane 6 occupies a position of equilibrium that holds it away from point 23. Once the injection stage takes place and the pressure of the fluid becomes sufficient to deform membrane 6, the latter is pressed hard against point 23 and is perforated (FIG. 8). Nonetheless, injection can be pursued normally as the point blocks the perforation and prevents the fluid from entering chamber 21. At the end of injection, joint 4 remains integral with the plunger, as seen earlier, but if it is attempted to draw in fluid again with a view to another injection, the perforation of membrane 6 will make this operation impossible. Air will, in fact, have been able to pass through ports 20, 22 and the perforation, and to penetrate to the bottom of the syringe, definitively preventing the application of any negative air pressure and any possibility of drawing in fluid. Non-return device 16 or any other system obstructing the syringe on the upper portion but allowing the plunger to slide also prevents any interference with the syringe in all the cases described.

According to yet another form of embodiment, illustrated in FIG. 9, clamp 13, used in accordance with the third form of embodiment in conformity with FIGS. 5 and 6, has on its lower portion a protuberance 24 which can have the shape of a tip with a rounded end. When the joint is mounted, steps are taken to ensure that the protuberance 24 is on the other side of membrane 6 in relation to the clamp, the tip of the protuberance passing through a central hole provided on the membrane.

The clamp and the membrane are thus rendered integral.

Operation is identical with that described in connection with the form of embodiment of FIGS. 5 and 6, that is the bulging of membrane 6 at the time of injection pushes upwards clamp 13 the jaws of which could close up in groove 12. If a user attempts to extract plunger 2, the driving of clamp 13 will draw out protuberance 24, unblocking the hole provided on the membrane, and there will remain this hole in joint 4 which will represent, in addition to the joint and the plunger being detached from one another, an additional deterioration of the joint rendering it inoperative. It will be noted that the protuberance can be withdrawn through the membrane owing to forces of friction of the joint in the syringe barrel being greater than the force of retention of the protuberance by the hole in the membrane. We thus come back to the cases illustrated in FIGS. 1 to 4.

A supplementary advantage of this variant is that the clamp is thus perfectly positioned in relation to the joint.

The devices thus described can be adapted to all types of syringes. Apart from the fact that they are perfectly efficient and strictly prevent reutilization of the syringes equipped therewith, they are simple to make and thus inexpensive.

We claim:

1. A disposable syringe comprising:

a cylindrical syringe barrel;

means for attaching a needle at one end of said syringe barrel;

a plunger mounted for movement toward and away from said one end of said syringe barrel;

a hollow member mounted at one end of said plunger for sliding movement internally of said syringe barrel, said hollow member including a deformable element disposed between said plunger and said one end of said syringe barrel, said deformable element is disposed in one position and capable of displacement to a second position upon movement of said plunger toward said one end of said syringe barrel, said deformable element having an orifice:

at least one external rib on said hollow member providing a seal between said hollow member and an internal surface of said syringe barrel: and

closing means located between said plunger and said deformable element of said hollow member, said closing means closing said orifice when said deformable element is initially in said one position, and movable to a second position in response to movement of said deformable element to said second position to prevent a second aspiration of a liquid following a first aspiration of liquid by movement of said plunger away from said one end of said syringe barrel whereby said closing means disengages from and opens said orifice upon corresponding displacement of said deformable element from said second position.

2. A disposable syringe comprising:

a cylindrical syringe barrel;

means for attaching a needle at one end of said syringe barrel;

a plunger mounted for movement toward and away from said one end of said syringe barrel;

a hollow cylindrical member mounted at one end of said plunger for sliding movement internally of said syringe barrel. said hollow member including an annular shaped upper portion which bears against said plunger and a flexible membrane forming a surface facing said one end of said syringe barrel and disposed between said plunger and said one end of said syringe barrel, said flexible membrane is disposed in one position and capable of displacement to a second position upon movement of said plunger toward said one end of said syringe barrel;

an orifice in said flexible membrane;

at least one external rib on said hollow member providing a seal between said hollow member and an internal surface of said syringe barrel; and

closing means located between said plunger and said flexible membrane of said hollow member, said closing means closing said orifice when said flexible membrane is initially in said one position, and movable to a second position in response to movement of said flexible membrane to said second position to prevent a second aspiration of a liquid following a first aspiration of liquid by movement of said plunger away from said one end of said syringe barrel, whereby said closing means opens said orifice upon corresponding displacement of said flexible membrane from said second position.

3. A disposable syringe according to claim 2, wherein the closing means follows the movement of said flexible membrane through pressure built up at the time of injection, and said closing means is retained by an immobilizing means in a position in which said closing means opens the orifice, breaking a seal between a top and bottom of the hollow member, as soon as the flexible membrane returns to an initial position.

4. A disposable syringe according to claim 3, wherein the closing means is mounted inside a hollow rod bearing an internal shoulder which extends the plunger and includes a closing head at the end of said hollow rod which closes the orifice provided in the flexible membrane.

5. A disposable syringe according to claim 3, wherein the immobilizing means for immobilizing the closing means are constituted by elastic strips borne by said closing means and folded back inside a hollow rod, said elastic strips gripping an internal shoulder of the hollow rod when the closing means has been displaced by deformation of the flexible membrane.

* * * * *

United States Patent [19]

Borras et al.

[11] **Patent Number: 4,973,308**

[45] **Date of Patent: Nov. 27, 1990**

[54] **INJECTION SYRINGE WITH MECHANISM PREVENTING REUSE**

[75] Inventors: **Ramón C. Borras; Ramón M. Rovira,** both of c/Juan XXIII n. 15-19, Barcelona, Spain, 08950

[73] Assignees: **Ramón M. Rovira; Thermacrome de España S.A.; Ramón C. Borras,** all of Barcelona, Spain; part interest to each

[21] Appl. No.: **194,970**

[22] Filed: **May 17, 1988**

[30] **Foreign Application Priority Data**

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Dec. 9, 1987 [ES] Spain 8703522

[51] **Int. Cl.**[5] **A61M 5/18**
[52] **U.S. Cl.** **604/110; 604/228**
[58] **Field of Search** 604/110, 187, 218, 228, 604/229, 231

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Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Ralph Lewis
Attorney, Agent, or Firm—Fleit, Jacobson, Cohn, Price Holman & Stern

[57] **ABSTRACT**

Disposable syringe for injecting fluids having a tubular body (1), a working stem (5) coupled to a piston (4), with a clearance between them, whereby movements of stem (5) determine relative corresponding displacements, of a determined length, between stem (5) and piston (4). A built-in tubular auxiliary element (8) is attached to the piston (4) and stem (5) by a sliding friction toothed attachment, which, depending on such relative displacements, advances within the syringe in uniform increments unidirectionally. Predetermined displacement of element (8) causes the syringe to become unserviceable. Built-in configurations (9), (13) and (14) prevent movement between the stem and piston as well as withdrawing of these elements from the body (1) until use of the syringe.

9 Claims, 4 Drawing Sheets

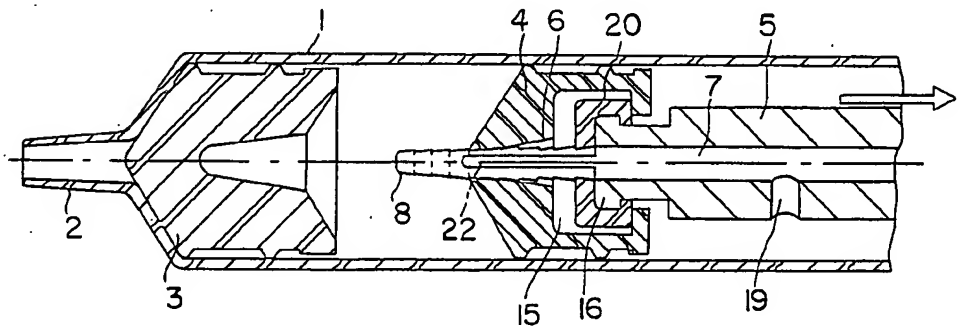
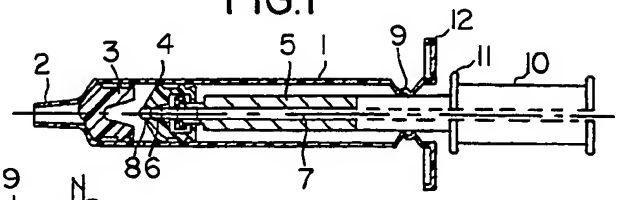


FIG.1



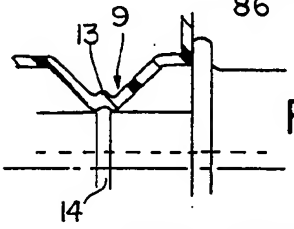


FIG.2

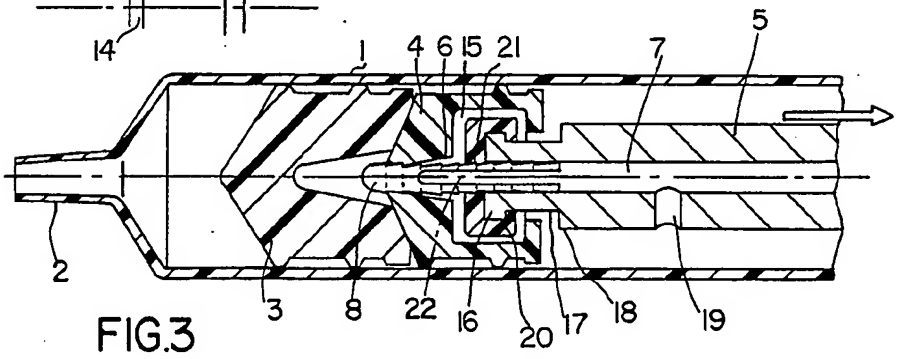


FIG.3

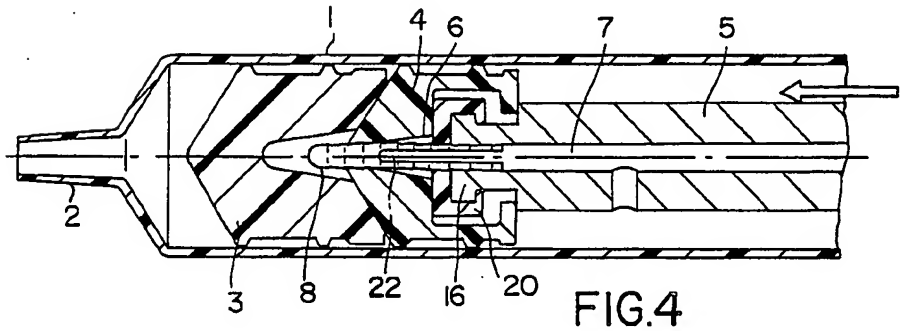
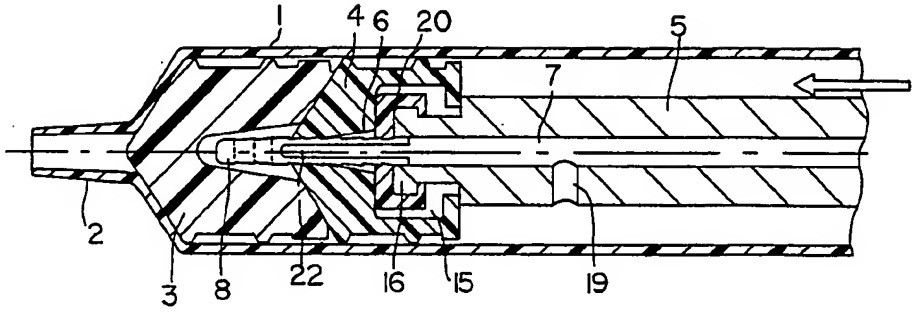


FIG.4

FIG.5



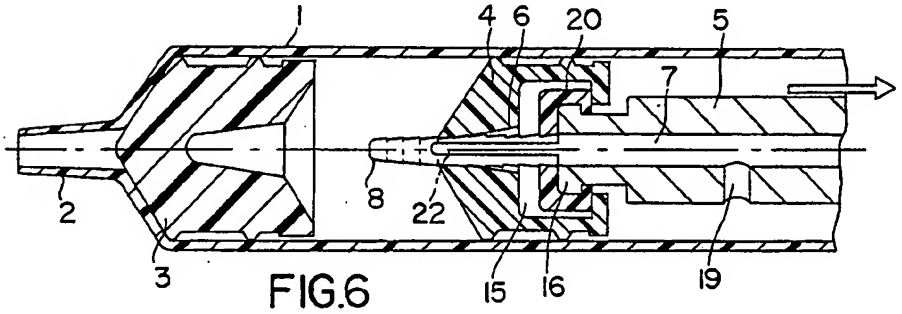


FIG.6

FIG.7

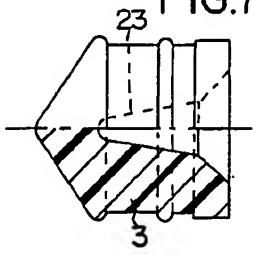


FIG.8

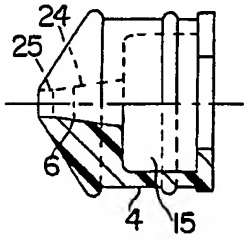
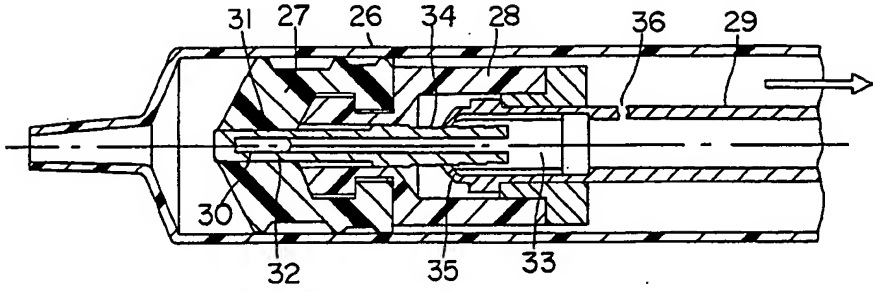


FIG.9



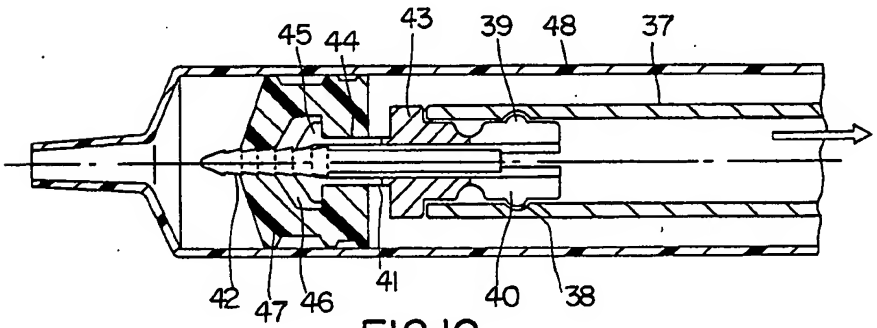


FIG.10

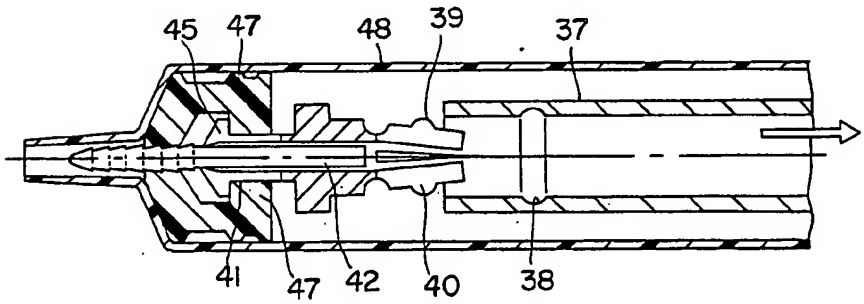


FIG.11

FIG.12

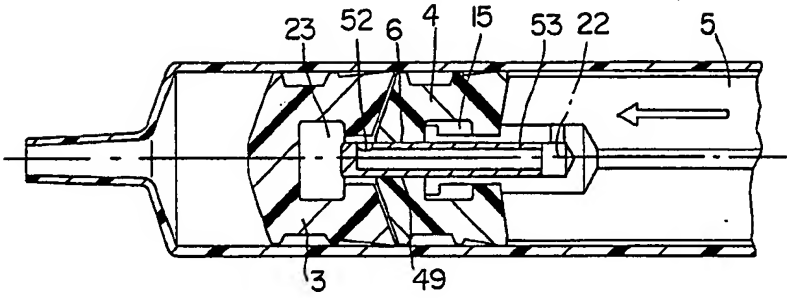


FIG.13

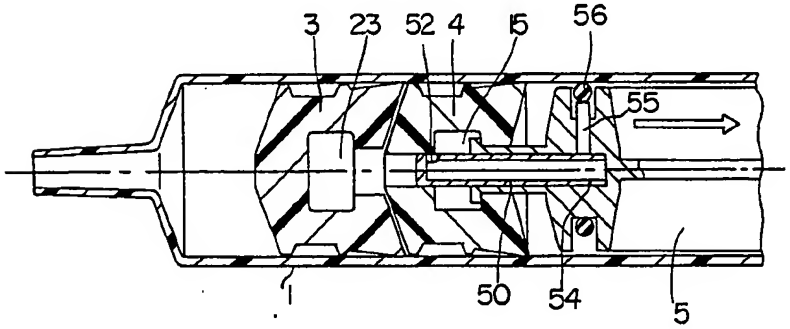
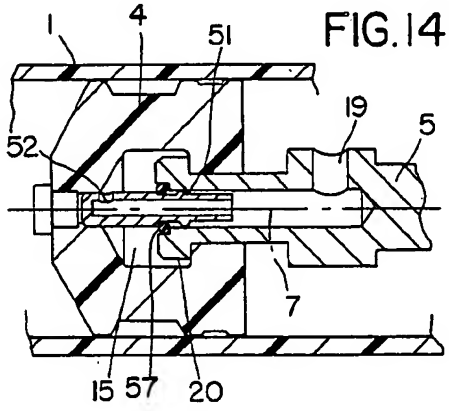


FIG.14



INJECTION SYRINGE WITH MECHANISM PREVENTING REUSE

BACKGROUND OF THE INVENTION

This invention relates to a disposable syringe for injecting fluids, and more particularly to a syringe having a device as a part there of which makes the syringe unserviceable once it has been used, and therefore assures that it is disposed of and not reused, and thus is specially designed to reduce the risk of transmission of infectious illness.

The syringe of this invention is in its general structure, fully equivalent to those presently in use; it shall be presented according to standards, in sterile packages, and, due to its special constitutive features compelling only a single use, it guarantees utilization, in any case, with the highest sanitation conditions.

In addition, this syringe has a production cost similar to that of conventional syringes, as it incorporates only one or two additional pieces, depending on the particular embodiment, which are easy to obtain.

Syringes are known that have built-in deposit, or deposits, containing products to apply though such syringes because of their structure, cost and operation, are completely different from the invention. Examples of such syringes are shown in U.S. Pat. No. 3,941,128, Australian Patent No. 16,859, Spanish Patent No. 531,282 and French Patent No. 2,298,340. However this syringe in order to be made unserviceable depends on voluntary action by the user.

BRIEF SUMMARY OF THE INVENTION

The object of the invention is to provide a syringe having an elongated hollow tubular body finished at one end by a duct adapted to receive a hollow needle connected to the inside of the duct, the tubular body having a biased end, and having in its interior a slidably mounted piston, tightly fitted and attached to a working stem. Up to this point the matter described is a fully conventional structure with component parts, wherein an end portion of the working stem is interlocked with a solid body portion by an attachment that provides bidirectional movement, of a confined length, of such end portion of the stem, with respect to the stem, or solid body portion corresponding to the movement of the working stem.

The syringe of the invention is characterized in addition by integrating an auxiliary element slidably mounted in the tubular body and associated by its two ends with specific friction or gearing attachments to the piston and working stem end. To achieve this, differentiated means are provided for retaining and passing the auxiliary element through a piston and the end portion of the stem which, due to the clearance between the stem and piston when operating the syringe, thereby subject these parts to some stresses determining related linear displacements for advancing the auxiliary element in a single direction. This auxiliary element adopts a configuration which is auxiliary to the unidirectionality and length of its incremental displacements within the tubular body.

The unit formed by the working stem, piston and auxiliary element, constitutes a device which makes it possible to activate different actuators to make the syringe become unserviceable after a number of preestablished sequences. Thus, for example, after a number of programmed predetermined displacements in two opposite directions, consecutively, of the working stem, in the conventional operation of the syringe, the auxiliary element is displaced to a point producing unserviceability of the aspiration function of the syringe, or preventing the drive of the stem on the piston.

The syringe body has some built-in means, such as a locking configuration, to avoid relative accidental movement between the working stem and the piston until the moment of using the syringe. Also, a configuration of the mouthpiece, or of another part of the syringe, is provided that prevents withdrawal of the piston and/or working stem from inside the tubular body.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of the invention is given below with reference to the accompanying drawings showing some preferred embodiments, which are to be understood only as illustrative and non-limitating, examples wherein:

FIG. 1 is a longitudinal cross-sectional view of an embodiment of the syringe according to this invention;

FIG. 2 is an enlarged detail of part of FIG. 1 showing the working stem locking with the wall of the tubular body of the syringe until the moment of using the syringe;

FIGS. 3 to 6 are enlarged views of a part of FIG. 1 showing the invention in different operative positions including the moment its unserviceability occurs;

FIG. 7 is a partial cross-sectional view of one of two pistons used in the syringe of the invention;

FIG. 8 is a view similar to FIG. 7 showing the other of the two pistons;

FIG. 9 is a view similar to FIG. 3 showing a further embodiment of the syringe of the invention in which the working stem remains attached to a rigid body which in turn is coupled to the piston and showing as well an alternative configuration of the auxiliary element and its fastening means;

FIGS. 10 and 11 are views similar to FIG. 9 showing a different embodiment of the syringe of the invention in which the displacement of the auxiliary element produces separation between the working stem and piston;

FIGS. 12 and 13 are views similar to FIG. 9 which show two further embodiments of the syringe of the invention characterized by forms of the auxiliary element adapted for retaining on the working stem; and

FIG. 14 is an enlarged detail of a further embodiment characterized by a certain configuration of the auxiliary element and attachment means at the working stem end.

DETAILED DESCRIPTION

Referring to FIG. 1, the syringe of the invention has a tubular body or cylinder 1, finished at one of its ends by a duct or nozzle 2 adapted to receive by connection thereto a conventional hollow needle, not shown. Inside body 1, is a first loose piston 3 and a second piston 4 attached to working stem or drive piston rod 5, the two elements 4, 5 having ducts 6, 7, respectively, aligned along the axis of body 1, in which are respectively introduced, with frictional attachment, the ends of an auxiliary element 8, element 8 being slidably mounted in elements 4, 5 for advancing therethrough in a single direction in uniform increments. In FIG. 1 it is observed that near the mouthpiece of the tubular body 1 is a throttle 9, or annular reduced diameter section (FIG. 2) made after assembly inside body 1 of elements 4, 5 and 8, and produced for example by a thermal

forming operation, where tubular body is made of a fitted thermoplastic material.

In addition FIG. 1 shows handle 10 of working stem 5 having an annular rib 11 that functions as a stop for limiting advance of stem 5 when it engages a flange 12, for example, on the mouthpiece of the syringe, according to a conventional configuration and to ease handling of the syringe

In FIG. 2, we can see that in the internal face of throttled area 9 of tubular body 1 an annular offset 13 is provided corresponding positionally to a coaxial rib 14 on working stem 5 constituting a tongue and groove configuration, for interlocking, that prevents accidental displacements between stem 5 and piston 4, before using the syringe. When intentionally drawing on stem 5 by handle 10 such locking means are uncoupled, for which purpose both elements are made of resilient materials.

FIG. 3 shows in larger detail that inside piston 4 a cavity 15 is defined wherein is housed and retained a larger end 16, of stem 5. The configuration of the stem 5 end portion includes a length of reduced diameter section 17 attached to straight step 18 which determines that all the inner and outer movements of stem 5 displace its larger end 16 an equivalent distance inside cavity 15 and relative to piston 4, such distance being confined by the length of smaller section 17, and/or the span of the cavity 15, before stem 5 drives or pushes piston 4.

FIG. 3 also shows axial duct 7 in stem 5 with an outlet 19, for atmospheric intake and also cap 20 of resilient material coupled to and covering larger end 16 of stem 5. This cap 20 has a passage hole 21 that remains facing duct 7 and through which is arranged tubular auxiliary element 8 having its external face stepped by a plurality of adjacent frustoconically shaped sectors, and having a linear groove 22 extending part way along its length from one of its ends. The other end of element 8 is inserted into the frustoconically shaped part and the adjoining cylindrical part of hole 21 where element 8 establishes an adjustable but tight fitting engagement. Piston 4 is made of a resilient material with operating conditions different from those of cap 20. Due to the orientation of the frustoconically shaped steps of auxiliary element 8 as shown in FIG. 3, which shows the first stage of the operation of the syringe. In this position element 8 has sealed the interior of piston 3 and tube 1 from the atmosphere so that retracting movement of piston 4 retracts piston 3 with it by creating a vacuum in chamber 23 and between the pistons. When working piston 5 is retracted auxiliary element 8 remains fixed by greater friction attachment in the cylindrical end section of duct 6, while cap 20, made of material resiliently weaker than piston 4, together with end 16 of stem 5 is retracted relatively to piston 4 and auxiliary element 8, passing over a step of this element.

A further inward movement of stem 5 will advance auxiliary element 8, in the duct 6, as shown in FIG. 4, because element 8 cannot go backwards through hole 21 of cap 20 since the latter is supported against larger portion 16 of stem 5 and the stepped configuration of element 8 prevents it.

In this way, each consecutive forward and backward movement of working piston 5 corresponds to one step incremental movement of auxiliary element 8 for advancing element 8 along piston 4.

When groove 22 of auxiliary element 8 reaches the inner end of duct 6 of piston 4, as shown in FIG. 5, groove 22 allows communication with the atmosphere, through its passage and through the ducts 7 and 19, of the space enclosed between pistons 3 and 4. Thus, as shown in FIG. 6, piston 3 cannot be further operated backwardly, the loose piston 3 remains, and the suction function of the syringe becomes unserviceable.

FIGS. 7 and 8 show the pistons 3 and 4, the former having a cavity 23 to allow the displacement therein of auxiliary element 8. In piston 4 large cavity 15 communicates through duct 6 with the inner end of piston 4, duct 6 having a frustoconically shaped portion 24 ending in cylindrical section 25 in order to establish a tight adjustment facility on element 8 and provide a moderated frictional engagement therewith.

The operation of the disclosed syringe will be possible using a single piston, although in such case, when the auxiliary element 8 communicates the interior enclosure between tubular body 1 and piston 4 with the atmosphere, the syringe becomes unserviceable and if one tries to push on the piston, the liquid in front of it will pass to the other side of the piston, whereby effective injection becomes impossible.

Within the capabilities of this invention, is an arrangement of referred elements where the auxiliary element instead of advancing towards the end of the syringe where the needle is coupled, advances, step by step, as explained, but in the opposite direction. In this latter case, should the syringe integrate a single piston, the auxiliary element 8, whenever visible by protruding beyond the piston, would provide the user with a visible indication that the syringe is still operative, while when disappearing inside the piston, it will clearly show that the stages this syringe provides are finished.

The form of the auxiliary element 8 is also to be considered as accessory, as well as the passage 19 for atmospheric intake, because considering that element 8 will advance in the opposite direction as explained, it could act as a simple tap establishing communication with the atmosphere of the enclosed area at the inner end of piston 4, once it is no longer supported at its end on the cylindrical section 25 of the duct 6, by means of duct 6 and a passage established through the annular wall of the cavity 15 in piston 4, for example.

The auxiliary element 8 must be located in every case, at the initial mounting position of this syringe, in an exact position, relative to piston 4 and stem 5, inserting it through duct 7 or duct 6, depending on its forward direction of advancement with the assistance of a gage-pusher (not shown).

FIG. 9 shows a syringe whose body 26 houses a single piston 27 slidably mounted in the inside, and attached to a hollowed out part 28, which has coupled in its inside the larger end of working stem 29. Associated by its ends to stem 29 and piston 27 is auxiliary element 30, constituted by a tube closed at one of its ends having a part housed, with frictional attachment, in a aisle 31 of piston 27 and having in its area remote from its closed end, one or several holes 32 that remain sealed during part of the lengthwise displacement of auxiliary element 30. The other end of element 30 remains housed in a tubular duct member 33 arranged at the end portion of stem 29 and has a stepped external configuration 34 in the form of frustoconical sections, which is engaged by a resilient clamping means in the form of pins or projections 35 embracing it, provided at the end of duct member 33. A gearing/frictional attachment is thereby obtained whereby retraction of stem 29 causes the clamping means to slip over one frustoconical section and inward movement engages the clamping means on ele-

ment 30 to push it inwardly. The stem 29 has an aperture 36 for atmospheric intake.

FIGS. 10 and 11 show an embodiment of the syringe where the working stem 37, in the form of a tube, has in the internal wall of an area near to its internal end an annular groove 38 where a rib ring profile 39 is coupled, rib 39 protruding from a single part 40 inserted in tube 37, and expanded by introducing through it a plane rod type section of an auxiliary element 41, the distal portion 42 of element 41 having an outer stepped wall that passes through piston 47. Expandable part 40, is continued by a double cylindrical portion 43 which is extended in turn by a reduced tubular throat section 44, ending in radial pins 45. Parts 44 and 45 remain retained inside the hollow interior 46 of piston 47, slidably mounted inside body 48 of the syringe allowing the displacement in two opposite directions of end portions 44, 45 of working piston 37.

In this embodiment, after a number of displacements of the working piston 37, the auxiliary element 41 has advanced through piston 47 and part 40 an leaves the inside of part 40, which thereafter not being expanded by element 41, releases rib ring 37 from groove 38 and thereby the working piston 37 from its association with the piston 47 as illustrated in FIG. 11.

FIGS. 12, 13 and 14 show some variants equivalent to the syringe of FIGS. 1 to 6, where only the form of the auxiliary element has been modified, marked in these figures by numerals 49, 50 and 51, as well as retaining means of such element, at the end of the working piston. For simplification parts numbers common to the other figures have been used.

In FIG. 12, the auxiliary element 49 is formed by a plain tube with a hole 52, with the end inserted in duct 6 of the piston 4, and its other end arranged inside a housing 53 of the end of stem 5 that has an outlet 22 for atmospheric intake.

The FIG. 13 embodiment is similar to that of FIG. 12, but the end 54 of the auxiliary element 50 is retained in the end portion of stem 5 by a pin 55, urged radially by resilient washer 56.

Finally, FIG. 14 introduces the variant of fastening the auxiliary element 51, of plain tubular configuration, at the end of stem 5 by means of an O-ring 57.

It is clear by all the disclosed embodiments herein, up to this point, that the essential features of the invention resides in a particular coupling between the working stem and the piston, which always produces a relative movement of the stem with respect to the piston, prior to displacement of the piston when operating the syringe. The auxiliary element advances in a single direction and engages by its two ends, by means of a differentiated working attachment, to the piston and stem. Because of the displacement of the auxiliary element, by its simplicity and effectiveness communication with the atmosphere of the interior area at the inner end of the piston is obtained to render the syringe unserviceable, and in suction function, although some other performances could be carried out, with results more or less equivalent, which must therefore be considered included in the invention.

Also means used to lock the working stem relative to the piston until starting the operation of the syringe are to be considered accessory, because though a tongue-groove configuration has been described for interlocking, many other industrially workable solutions are feasible, for example attaching the piston to the body of the syringe by a plastic microwelding, arranging a tap or fixing device at the end of the stem, etc.

As for means to prevent the stem and piston withdrawal, once installed in the syringe, although a throttle has been proposed in the mouthpiece area because of its simplicity, many other known solutions can be used with similar results and thus the one described is not to be understood as limitative.

For greatest security, material will be used to constitute the body of the syringe having properties capable of sustaining breakage or sawing stresses for the use intended.

Having disclosed the invention in this application in a sufficient manner in order that the essential features thereof are understood by a technician skilled in the art, the invention includes variations of detail not altering its features, such as different configurations of the stem 5, pistons 3, 4, auxiliary element 8, resilient element 20, locking means 13-14 and retaining means 9, fulfilling functions equivalent to that disclosed, the basic characteristics being summarized in appended claims.

We claim:

1. An injection syringe with device preventing reuse comprising:

a hollow syringe cylinder having a nozzle at one end adapted for connection to a hollow injecting needle, and being open at the other end;

a drive piston rod removably inserted into said open end of said cylinder for axial movement therein and having an inner end portion;

piston means sealingly and slidingly mounted within said cylinder between said one end and said drive piston rod for forcing fluid in said cylinder through said nozzle as said drive piston rod is urged inwardly towards said one end of said cylinder;

attachment means connecting said inner end portion of said drive piston rod with said piston means and providing relative bidirectional limited axial displacement between said piston means and said inner end portion of said drive piston rod;

an auxiliary element having sliding engaging means thereon for sliding engagement with said attachment means and with said piston means so that said auxiliary element is displaced axially with respect to said attachment means in a single direction by said bidirectional limited axial displacement produced by reciprocating axial movement of said drive piston rod; and

means for preventing further use of the syringe after predetermined axial displacement of said auxiliary element.

2. An injection syringe as claimed in claim 1 wherein:

said piston means has an inner face facing said one end of said cylinder;

said attachment means comprises a hollow cavity within said piston means, a substantially radially extending end element on said inner end portion of said drive piston rod disposed within said cavity having an axial dimension smaller than that of said cavity to facilitate said bidirectional limited axial displacement between said piston means and said inner end portion of said drive piston rod;

first duct means extend through said inner end portion of said drive piston rod and through said end element communicating with said cavity;

second duct means extends through said piston means and the inner face thereof communicating with cavity with the hollow interior of said cylinder

between said piston means and said one end of said cylinder;

vent passage means is provided communicating with said first duct means;

said auxiliary element comprises a pin member disposed partly in said first duct means and partly in said second duct means, and a groove in the outer surface of said pin member extending substantially axially a predetermined part of the length thereof; and

said sliding engaging means comprises a toothed configuration on the outer surface of said pin member facilitating movement of said pin member through said inner end of said drive piston rod and said piston means in a single direction only, so that said pin member moves at least a distance sufficient for a part of said groove to extend through said inner face of said piston means to communicate the hollow interior of said cylinder between said piston means and said one end of said cylinder with said duct means and said vent means for preventing further use of the syringe.

3. An injection syringe as claimed in claim 2 wherein:

said toothed configuration comprises a plurality of truncated cones disposed relatively axially with respect to each other with the smaller bases thereof forward of the larger bases in the direction of said one end of said cylinder.

4. An injection syringe as claimed in claim 4 wherein:

each truncated cone has a height between the bases thereof substantially corresponding to said limited axial displacement between said piston means and said inner end portion of said drive piston rod.

5. An injection syringe as claimed in claim 2 and further comprising:

an auxiliary piston means slidingly and sealing mounted in said syringe cylinder between said piston means and said one end of said cylinder;

a rear face on said auxiliary piston means cooperatively engaging said inner face on said piston means prior to said predetermined axial displacement of said auxiliary element so that at least a partial vacuum is effected between said piston and auxiliary piston means and said auxiliary piston means adheres to said piston means during operation of the syringe until said auxiliary element is displaced an amount equal to said predetermined axial displacement relative to said piston means to cause release of said at least partial vacuum and disengagement of said faces whereby said auxiliary piston means is retained in said cylinder for preventing reuse of the syringe.

6. An injection syringe as claimed in claim 5 and further comprising:

a cavity in said auxiliary piston extending inwardly thereof from said rear face.

7. An injection syringe as claimed in claim 2 wherein:

said inner end portion on said drive piston rod comprises a radially enlarged end; and

said substantially radially extending end element comprises a resilient end cap at least partially enclosing said enlarged end for being retained thereon.

8. An injection syringe as claimed in claim 1 and further comprising:

an inner face on said piston means facing said one end of said cylinder;

an auxiliary piston means slidingly and sealing mounted in said syringe cylinder between said piston means and said one end of said cylinder;

a rear face on said auxiliary piston means cooperatively engaging said inner face on said piston means prior to said predetermined axial displacement of said auxiliary element so that at least a partial vacuum is effected between said piston and auxiliary piston means and auxiliary piston means adheres to said piston means during operation of the syringe until said auxiliary element is displaced an amount equal to said predetermined axial displacement relative to said piston means to cause release of said at least partial vacuum and disengagement of said faces whereby said auxiliary piston means is retained in said cylinder for preventing reuse of the syringe.

9. An injection syringe as claimed in claim 8 and further comprising:

a cavity in said auxiliary piston extending inwardly thereof from said rear face.

* * * * *

United States Patent [19]

Bailey

[11] **4,257,426**

[45] **Mar. 24, 1981**

[54] **VACUUM ASSISTED ANTI-COAGULANT SYRINGE DEVICE FOR TAKING BLOOD SAMPLES**

[75] Inventor: **Donald L. Bailey**, Thornton, Colo.

[73] Assignee: **Marquest Medical Products, Inc.**, Englewood, Colo.

[21] Appl. No.: **50,970**

[22] Filed: **Jun. 22, 1979**

[51] **Int. Cl.**[3] **A61B 5/14**

[52] **U.S. Cl.** ..... **128/766**; 73/425.6; 128/276; 128/218 P; 128/218 PA; 128/765

[58] **Field of Search** ..... 128/763-766, 128/218 P, 218 PA, 218 R, 276, 278; 73/425.6

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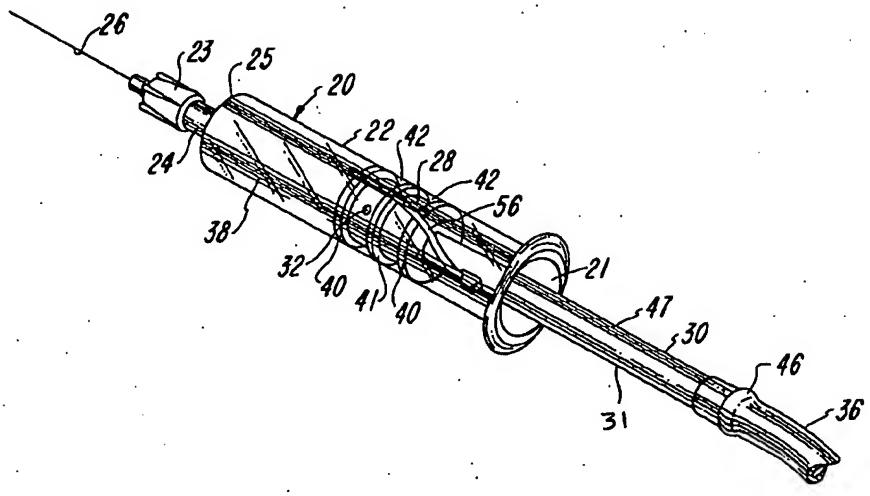
Primary Examiner—Kyle L. Howell

Attorney, Agent, or Firm—Gary M. Polumbus; Crandell & Polumbus

[57] **ABSTRACT**

A syringe device has a hollow tubular body that receives a resilient sealing member rotatably connected to a hollow plunger. A vacuum pump is connected through a flexible tube to the hollow plunger to thereby withdraw blood using the vacuum created. Once in the syringe body, blood is automatically exposed to an anti-coagulant stored within the syringe body. The anti-coagulant is in flake form and premanufactured from a heparin solution which is allowed to evaporate on a non-stick surface.

4 Claims, 8 Drawing Figures



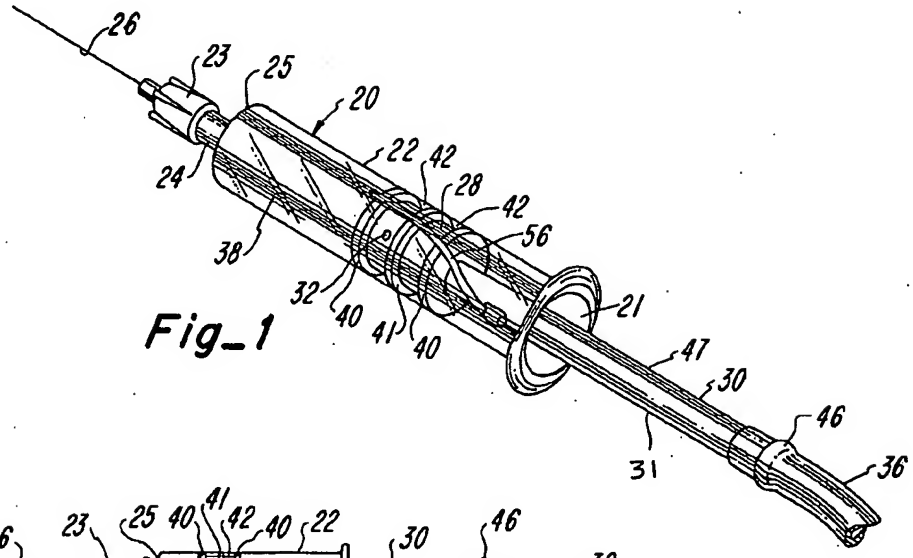


Fig_1

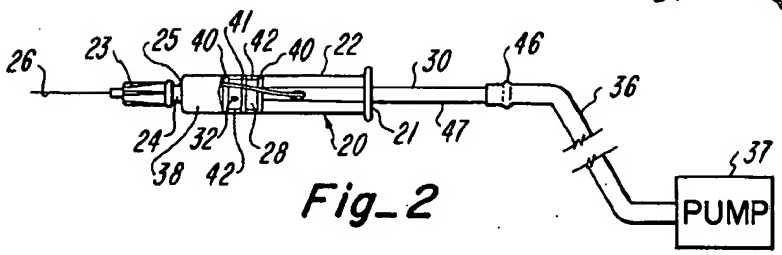


Fig_2

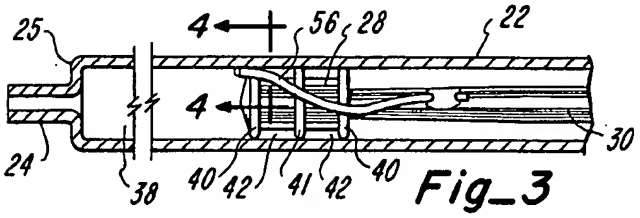


Fig_3

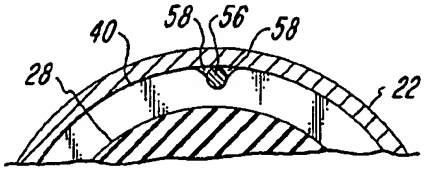


Fig_4

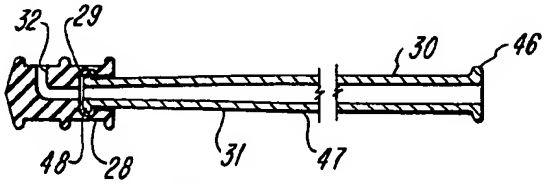


Fig_5

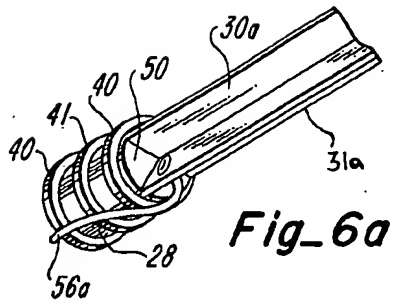


Fig_6a

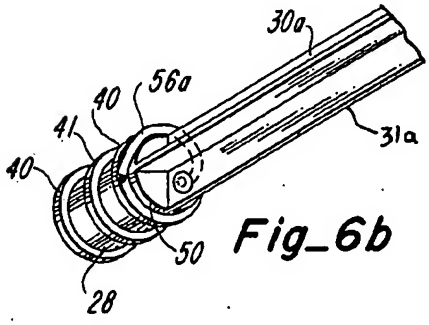


Fig_6b

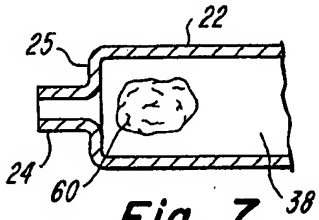


Fig_7

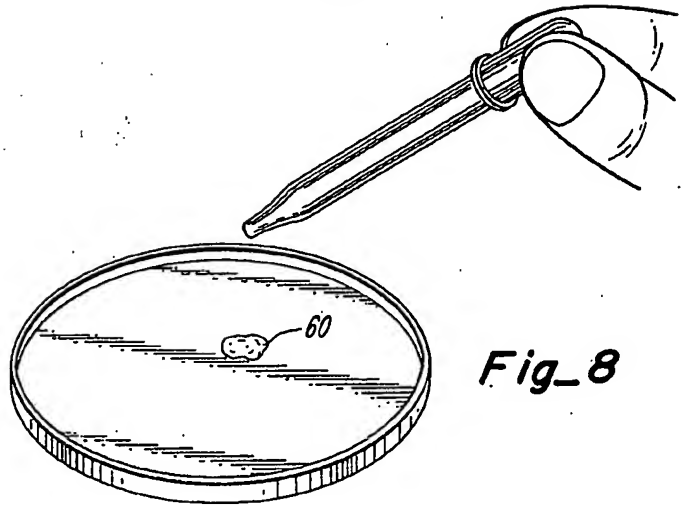


Fig_8

VACUUM ASSISTED ANTI-COAGULANT SYRINGE DEVICE FOR TAKING BLOOD SAMPLES

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to syringes for collecting blood samples, and more particularly syringes of the type that are assisted in drawing blood by a vacuum in the interior of the syringe.

2. Description of the Prior Art

Syringe type devices are typically used for obtaining blood samples to perform a blood gas analysis. In these tests it is important that air and other materials contained in anti-coagulant solutions, such as water which is a diluent for the heparin, are not allowed to contaminate the blood and distort the results of the gas analysis. Several syringe devices have been developed to obtain contaminant free blood samples. Examples of such syringe devices are disclosed in my pending U.S. patent application for a Syringe Device With Means for Selectively Isolating a Blood Sample After Removal of Contaminates and Method of Using Same, Ser. No. 952,994, filed Oct. 20, 1978 and in U.S. Pat. Nos. 3,978,846 and 4,133,304 of which I am also the inventor.

However, not all individuals have a blood pressure which is high enough to fill the body of a syringe to a preselected volume necessary to conduct blood gas analysis. This is particularly true with small babies, especially premature babies, whose blood pressure is so low that it is difficult to get any flow whatsoever into a conventional syringe device. The newborn or premature baby problem is further complicated by the size of the arteries and veins and incumbent restrictions on the gauge of the needle that must be used to penetrate the artery or vein. The small dimensions, necessarily encountered, of the needle, impede any blood flow that might be expected.

In obtaining blood samples it is necessary to use an anti-coagulant to maintain the integrity of the blood sample. Typically, a dilute heparin solution of 1,000 units per milliliter in alcohol and water has been placed within the syringe body prior to use, which, after evaporation, leaves a deposit of heparin within the syringe body. This process takes a period of time, as long as an hour, and thus, undesirably extends the manufacturing time of the syringe when the syringe is provided with the dried heparin coating therein.

SUMMARY OF THE INVENTION

The syringe device of the present invention includes a main tubular body, the trailing end of which slidably receives a combination sealing member and hollow plunger, with the plunger geing rotatably connected to the sealing member. The plunger is also connected to a vacuum pump through a flexible hose. The leading end of the tubular body frictionally receives a hypodermic needle through a short extension portion thereof so that the needle extends longitudinally away from the main tubular body. The extension has a central bore through which blood received through the hypodermic needle can pass into the main tubular body of the syringe. Each end of the sealing member has an enlarged diameter circular lip, and an intermediate circular lip is disposed between the end lips, so that contact sufficient to create a seal exists between the lips on the sealing member and the syringe body. The sealing member has a lateral vent between the lip nearest the leading end of the sealing member and the intermediate lip, with the vent being communicative with the hollow interior of the plunger, the hose and vacuum pump. A flexible thread fixed to the plunger selectively crosses the lips and breaches the seal created by the sealing member to establish communication between the interior of the plunger and the interior of the tubular body via the lateral vent in the sealing member. Removal of the thread allows a seal to be restored so that a gas free blood sample can be isolated in the hollow tubular body.

Dry flake heparin is prepared from a sodium heparin solution for use in the syringe so that the heparin flakes can be placed in the syringe without unduly delaying the manufacturing process of the syringe. The sodium heparin solution, in the proper proportions, is dropped onto a non-stick flat surface, such as Teflon, and allowed to evaporate leaving a residue of dry flake heparin. The heparin flakes can be placed within the tubular body for immediate use, or stored for later use.

The principal object of the present invention is to provide a syringe device capable of drawing predetermined amounts of contaminant free blood from individuals with low blood pressure or from minute veins or arteries.

A related object of the present invention is to provide a syringe that can draw a preselected volume of contaminant free blood by use of a small gauge hypodermic needle.

It is a further object of the present invention to provide a new and improved anti-coagulant syringe device ready for immediate use in obtaining contaminant free blood samples.

Another object of the present invention is to provide a syringe device that can collect a blood sample free of gaseous contaminants from air and anti-coagulant diluent reactions with blood.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the syringe portion of the present invention.

FIG. 2 is a plan view of the present invention with parts removed for clarity.

FIG. 3 is a fragmentary longitudinal section of the syringe portion of the invention with parts removed.

FIG. 4 is an enlarged fragmentary section taken along line 4—4 of FIG. 3.

FIG. 5 is a longitudinal section of with parts removed plunger.

FIG. 6*a* is a fragmentary perspective view of an alternative embodiment of the invention showing a flexible tube connected to the plunger and extending across the sealing member.

FIG. 6*b* is a view similar to FIG. 6*a* but showing the flexible tube wrapped onto the plunger and away from the sealing member.

FIG. 7 is a fragmentary longitudinal section of the syringe illustrating a heparin flake contained therein.

FIG. 8 is a perspective view of a flake of heparin formed on a non-stick surface.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1 of the drawings, a preferred form of the syringe 20 of the present invention includes a transparent or translucent main tubular body 22 of circular transverse section having an open trailing or rear-

ward end 21 and a reduced diameter end fitting or neck 34 protruding axially from a leading or forward end wall 25 of the tubular body to which a hypodermic needle 26 is frictionally connected by a needle connector 23 in a hermetically sealed relation. The neck 24 is hollow and communicates with an interior chamber 38, generally defined by the space in the tubular body 22, the leading end wall 25 and a hollow plunger 30 which is received in the tubular body 22 through the open trailing end 21. A plunger body 31 is rotatably mounted within a resilient sealing member 28, and both the plunger body and sealing member, forming in combination the plunger, are received through the open trailing end 21 of the tubular body. The sealing member 28 is further adapted to slide along the interior surface of the main tubular body 22 in a sealed relationship therewith. The trailing end of the plunger body 31, which is at the opposite end of the plunger from the end where the sealing member 28 is mounted, is connected through a flexible hose 36 to a vacuum pump 37 (FIG. 2). A flexible thread 56 is permanently fixed to the plunger body 31 and is positioned to selectively cross the sealing member 28 in a manner and for purposes to be described in more detail later.

The elongated rigid tube-like body 31 terminates at its trailing end in an annular flange 46 of slightly larger diameter than that of the tube-like body 31 (FIG. 5). The intermediate tubular body 31 has a second annular flange 48 on its leading end adapted to be rotatably received in a recess 29 of a 'T' shaped cross-section in the trailing end of the sealing member 28. The plunger body, therefore, has an elongated dumbbell appearance. The annular flange 48 is rotatably received within the recess 29 of the sealing member 28 so as to provide for rotation of the plunger body 31 relative to the sealing member 28. Rotation of the plunger body 31 winds the thread 56 onto the body and pulls it away from the sealing member 28, thereby allowing a hermetic seal to be established between the sealing member and the interior surface of the tubular body 22. When the thread is allowed to extend across the sealing member, it breaches the seal and allows fluids to flow across the sealing member as will be explained more clearly later.

The plunger body 31 is connected to the thread 56 by glue or similar adhesive. (FIG. 3.) The thread 56 is of sufficient length to be extended across integral circular sealing lips 40 disposed at either end of the sealing member 28. A third circular sealing lip 41 is intermediate to sealing lips 40. The thread 56 is made of flexible material, such as nylon or cotton and has a diameter sufficient to form a breach or space 58 between the sealing lips 40 and 41 and the interior surface of the syringe body 22 when the thread 56 is extended across the sealing member 28.

As mentioned previously, the plunger body 31 is rotatably received within the sealing member 28. The annular flange 48 combines with the mating shape of the recess 29 to allow the sealing member to be moved axially within the syringe body 22 by the plunger body 31 to establish the volume of the blood sample desired. The circular mating configuration between the annular flange 48 and mating recess 29 permit rotational movement of the plunger body relative to the sealing member 28, a required capability for winding the thread 56 and removing the breach points 58. With the thread extended across the sealing member, it is readily apparent that as a sample of blood is taken, pre-existing gases within the chamber 38 are purged from the chamber through the breach points 58. Once the inflowing blood crosses the breach points 58, the thread is wound onto the plunger body, permitting the lips 40 and 41 to return to an undeformed shape, hermetically isolating a gas free blood sample in the chamber 38.

The sealing member 28 portion of the plunger is constructed of a material having elastic and resilient properties such as rubber. In its undeformed shape, the sealing member is generally cylindrical with the circular peripheral lips 40 at either end, and the intermediate circular lip 41 disposed therebetween. The lips 40 and 41 are of sufficient diameter to contact the interior surface of the syringe body 22 and form a sliding hermetic seal therewith. A pair of cylindrical void spaces 42, are defined between the body of the sealing member 28, the lips 40 and 41 and the internal surface of the main tubular body 22. The sealing member has a lateral vent 32 establishing fluid communication between the recess 29 and the void space 42 nearest the leading end 25 of the tubular body. It follows that fluid communication is provided with the hollow plunger 30 and the interior chamber 38 through the breach points 58.

The lateral vent 32, and the hollow plunger body 31, define a fluid passageway between the leading end void space 42 and the ambient environment (FIG. 5). Access of that passageway to the interior chamber 38 across the sealing member 28 is provided by the flexible thread 56, which indents the lips 40 and 41 to form the breach points 58 at each lip. The passageway so defined can be used to draw a vacuum on the interior chamber 38, thereby assisting the flow of blood into the chamber through the needle 26.

Though three circular lips 40 and 41 have been disclosed in regard to the sealing member 28, a pair of lips 40 will also perform certain aspects of the present invention as already described in my copending application Ser. No. 952,994 Syringe Device with Means for Selectively Isolating a Blood Sample After Removal of Contaminants and Method of Using Same. The additional lip increases the frictional forces between the sealing member 28 and the interior surface of the main tubular body 22 by increasing the contact area therebetween. This becomes important as a vacuum is drawn in the interior chamber 38.

The flexible hose 36, which may be rubber, latex or the like, is adapted to flexibley fit over the annular flange 46 of the plunger body 31 and from there connect to the vacuum pump 37 (FIG. 2). The vacuum pump 37 has specifications such that it is capable of creating a vacuum in the interior chamber 38 of the tubular body of between 100 and 150 millimeters of mercury. The tight fit of the three sealing lips 40 and 41 prevent the vacuum in the chamber 38 from pulling the sealing member 28 and the connected plunger body 31 axially along the tubular body 22. In this manner, the preselected volume of chamber 38 is established by manually moving the sealing member 28 by means of the plunger along the interior surface. Once selected, this volume will not be altered as vacuum is drawn in the interior chamber 38. From the foregoing, it can be seen that as vacuum is drawn by the pump 37, pressure is lowered in the interior chamber 38, encouraging blood to flow from an individual's blood stream through the needle 26 into the chamber 38.

This feature of the present invention is particularly important in using the syringe device 20 of the type disclosed with individuals having low blood pressure or with extremely small infants having small veins and

arteries. The main advantage of the invention lies in the fact that once the sealing member 28 is set to a preselected position along the interior of the syringe body 22, a gas free blood sample can be collected regardless of the blood pressure of the individual from whom the sample is sought.

Additionally, a very small gauge needle, smaller than needles typically used in hospitals and health related organizations throughout this country, can be used routinely with the vacuum assist. The smaller gauge needle presents greater resistance to fluid flow than does the large gauge needle and therefore the use of a vacuum assist permits the use of smaller needles than would otherwise be possible.

The hypodermic needle 26 is connected to the syringe 22 at the end fitting 24 in a manner well known in the art. The entire syringe 20 and the parts thereof are made of presterilized glass materials which can be prepackaged and discarded after use, a procedure universally adopted in the health care industry.

In an alternative embodiment of the present invention, the thread 56 is replaced by a relatively short flexible and resilient tube 56*a*, which can be made of polyethylene (FIG. 6*a*). In this embodiment, two or three sealing lips may be used and vacuum assist though the hose 36 is not used. This is partially because a smaller diameter plunger body 31 must be used to fit the hose 36, and the tube 56*a*, which has a relatively small diameter itself, cannot be readily fixed to it. The interior chamber 38 is filled with blood by the individual's blood pressure alone. On low blood pressure individuals, the sealing member 28 is set at a relatively low volume setting such as 0.1 to 0.2 CC, and blood is allowed to flow into the chamber. After the low volume chamber is completely full of blood and blood begins to pass through the breach points 58, the breach points are eliminated by winding the tube 56*a* onto the plunger body 31*a* (FIG. 6*b*), and the plunger 30*a* is then pulled out relative to the tubular body 22 enlarging the size of the chamber 38 and simultaneously withdrawing blood until the proper volume is achieved.

The tube 56*a* of the alternative embodiment is tied to the plunger body 31, preferably near a disc 50 attached to the plunger adjacent to the connection location of the plunger body to the sealing member 28. The tube 56*a* then can be extended across the sealing member 28 in a manner as described with the thread 56. It has been found that one desirable feature of the tube 56*a* is that it spreads the forces between the sealing member 28 and the interior of the syringe body 22 over a greater area, whereby permanent deformation of the sealing member 28 is less likely to occur. This becomes a significant advantage when syringes 20 are stored for extended periods of time.

It is of course necessary to make sure that the blood sample taken does not coagulate and ruin the results of analyses taken on the sample. Typically an anti-coagulant, such as heparin, is utilized to coat the interior chamber 38 of the tubular body. A solution of anti-coagulant, in the past, has been placed in the chamber and allowed to evaporate leaving a dried anti-coagulant precipitate in the interior chamber 38. The heparin solution is typically very dilute, the heparin concentration being 1,000 units per milliliter in a diluent of alcohol and water.

Part of the present invention relates to pre-preparation of a dry flake of heparin 60 through a new and unique process and placing it in a dried state in the interior chamber 38 so that any blood received is immediately exposed to the heparin. It has been found that a solution of water and sodium heparin can be evaporated on a flat non-stick surface, such as Teflon, leaving a dry flake 60 FIG. 8) of heparin. Specifically, it has been found that a solution formed from a concentration of 3,000 or more units of sodium heparin per milliliter of water achieves the desired results. After formed, 20 to 60 microliters of that solution are allowed to evaporate leaving a dry residue having a concentration of 60 to 180 units of heparin.

The flake so produced has obvious advantages over prior methods due to the fact that the heparin flake 60 can be stored along with the tubular body 22 for immediate use of the syringe 20 (FIG. 7.) or the heparin flake can be produced prior to the syringe, and merely dropped in the syringe prior to storage. Prior methods were limited by a waiting period for the production of dried heparin in the syringe body.

OPERATION

After the heparin flake 60 has been placed in the body 22 of the syringe, the thread 56 is extended completely across the sealing member 28, slightly indenting all lips 40 and 41 and forming breach points 58. The plunger body 31, sealing member 28 and thread 56 are slidably inserted into the syringe body 22 through the open circular end 21 of the syringe 20. The plunger body 31 is used to position the sealing member 28 at a point along the tubular body 22 corresponding to the volume of blood sample desired. Typically, syringe bodies 22, are calibrated in volummetric units in order to facilitate this purpose.

The hypodermic needle 26 is frictionally connected to the neck 24 and is inserted into the artery of the donor patient where the blood pressure will normally force the blood through the needle 26 into the interior chamber 38 of the syringe body 22. The individual taking the sample should orient the syringe so that the breach 58 in the seal lip 40 nearest the needle 26 is disposed so as to be at the furthest distance possible from the rising level of the blood as it enters the interior chamber 38. The sealing member 28 thus acts as a dam and the breach created by the thread 56 or polyurethane tube 56*a* serves as a vent for air and gases which were pre-existant in the body 22 or were created by reaction of the blood with the anti-coagulant flake 60. Ultimately, after the interior chamber 38 is filled with blood, the breach 58 serves as a spillway through which the blood can pass into the void space 42. It will be appreciated that as the blood fills the interior chamber, the chamber is purged of all gaseous materials that might contaminate the blood sample.

As the blood reaches the point 58 and crosses the first lip 40 into the void space 42, the plunger body 31 is rotated so as to wind the thread 56 or tube 56*a* about the plunger body 31*a* thus pulling the thread past the forwardmost sealing lip 40 establishing a complete seal at that location. Continued rotation of the plunger body 31 will pull the thread 56 or tube 56*a* past the remaining lip or lips 40 and 41 of the sealing member 28 thus establishing a complete seal at that location to trap the blood that flowed into the void space 42 and thus prevent leakage of any blood from the syringe 20.

The present invention is adapted for use with individuals having extremely low blood pressures. Absent vacuum assist, the procedure described with reference to use of the polyethylene tube 56*a* should be used.

When vacuum assist is available, the hose 36 is attached to the flange 46 of the plunger body 31. Actuation of the vacuum pump 37 creates a vacuum of between 100 and 150 milliliters of mercury in the interior chamber 38 of the syringe 20. Blood is thus drawn into the interior chamber 38 when it might not ordinarily flow. This procedure is also particularly useful in treating infants, where a very small gauge needle, smaller than normally used in hospitals and medical facilities, can be utilized to enter the very small veins or arteries of a baby. Normally, such a small gauged needle constricts blood flow and would not permit the interior chamber 38 to be filled by even normal blood pressure.

It will be understood that changes may be made in details of construction, arrangement and operations without departing from the spirit of the invention, especially as defined in the appended claims.

What I claim is:

1. A syringe device of the type used for drawing blood samples, the device having a generally tubular body with an open rearward end and a forward end adapted to receive a hypodermic needle in a manner to establish fluid communication between said needle and the interior of said tubular body, a plunger adapted to be slidably positioned within said tubular body to define a preselected volume within the tubular body, said plunger including a hollow elongated body, a resilient sealing member rotatably connected to the elongated body having a vent therethrough in communication with the hollow interior of said plunger body, and seal interruption means allowing communication between the vent of said sealing member and the interior of said tubular body forwardly of said sealing member, a flexible hose operably connected to said elongated body to establish fluid communication between the interior of said elongated body and the flexible hose, and vacuum pump means operatively connected to said hose whereby pressure can be lowered within the interior of said tubular body forwardly of said sealing member to thereby draw blood into the syringe when said seal interruption means is operative to allow communication between the vacuum pump means and the interior of said tubular body forwardly of said sealing member.

2. The invention defined in claim 1 wherein the interior of said tubular body has contained therein a dry flake of heparin.

3. The invention defined in claim 1 wherein said sealing member is of generally cylindrical shape having a an forward end circumferential lip, a rearward end circumferential lip, and an intermediate circumferential lip between said end lips, said lips adapted to fully contact said tubular body's interior surface.

4. The invention defined in claim 3 wherein said transverse vent is located between the forward end lip and the intermediate lip.

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L Number	Hits	Search Text	DB	Time stamp
1	1900	lee.in. with robert	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:47
2	0	loethe.in. with brian	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:47
3	1	koethe.in. with brian	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:47
4	1	swaback.in. with theodore	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:47
5	1900	(lee.in. with robert) (koethe.in. with brian) (swaback.in. with theodore)	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:47
6	30	((lee.in. with robert) (koethe.in. with brian) (swaback.in. with theodore)) and syringe	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:49
9	1	09/584307	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:54
10	17	("3810469" | "4254768" | "4506455" | "4693706" | "5435076" | "5531683" | "5643218" | "5685846" | "5697915" | "5709666" | "5743886" | "5769825" | "5779668" | "5788670" | "5833653" | "5865803" | "5971953").PN.	USPAT	2004/01/25 16:50
11	8	("3672369" | "4030498" | "4632672" | "4846801" | "5125898" | "5238003" | "5318536" | "5489266").PN.	USPAT	2004/01/25 16:52
13	610	604/228	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:55
14	324	((604/228) or (604/231)).CCLS.	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:55
15	706	604/228 (((604/228) or (604/231)).CCLS.)	USPAT; US-PGPUB; EPO; JPO	2004/01/25 16:55
16	632	(604/228 (((604/228) or (604/231)).CCLS.)) and @PD<=20011221	USPAT; US-PGPUB; EPO; JPO	2004/01/25 17:17
17	6	("4059109" | "4233975" | "4687487" | "4863427" | "4880410" | "4973308").PN.	USPAT	2004/01/25 17:08
19	876	(syringe with vent$) and @PD<=20011221	USPAT; US-PGPUB; EPO; JPO	2004/01/25 17:18
21	262	(syringe same (plunger piston) with vent$) and @PD<=20011221	USPAT; US-PGPUB; EPO; JPO	2004/01/25 17:19
22	240	((syringe same (plunger piston) with vent$) and @PD<=20011221) not ((604/228 (((604/228) or (604/231)).CCLS.)) and @PD<=20011221)	USPAT; US-PGPUB; EPO; JPO	2004/01/25 17:19